

1 when a request for records pursuant to such section
2 704(a)(4) was not issued or complied with.

3 ~~“(6) The number of facilities that did not im-~~
4 ~~plement requested corrective or preventive actions~~
5 ~~following a report issued pursuant to such section~~
6 ~~704(b), resulting in a withhold recommendation, in-~~
7 ~~cluding the number of such times for each category~~
8 ~~of drugs listed in subparagraphs (A) through (C) of~~
9 ~~paragraph (1).”.~~

10 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

11 (a) *SHORT TITLE.*—*This Act may be cited as the*
12 *“Food and Drug Administration Safety and Landmark Ad-*
13 *vancements Act of 2022” or the “FDASLA Act of 2022”.*

14 (b) *TABLE OF CONTENTS.*—*The table of contents for*
15 *this Act is as follows:*

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use drug fees.

Sec. 104. Reauthorization; reporting requirement.

Sec. 105. Sunset dates.

Sec. 106. Effective date.

Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

Sec. 201. Short title; finding.

Sec. 202. Definitions.

Sec. 203. Authority to assess and use device fees.

Sec. 204. Reauthorization; reporting requirement.

Sec. 205. Accreditation programs.

Sec. 206. Sunset dates.

Sec. 207. Effective date.

Sec. 208. Savings clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.*
- Sec. 302. Authority to assess and use human generic drug fees.*
- Sec. 303. Reauthorization; reporting requirements.*
- Sec. 304. Sunset dates.*
- Sec. 305. Effective date.*
- Sec. 306. Savings clause.*

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.*
- Sec. 402. Definitions.*
- Sec. 403. Authority to assess and use biosimilar biological product fees.*
- Sec. 404. Reauthorization; reporting requirements.*
- Sec. 405. Sunset dates.*
- Sec. 406. Effective date.*
- Sec. 407. Savings clause.*

TITLE V—IMPROVING REGULATION OF DRUGS AND BIOLOGICAL PRODUCTS

- Sec. 501. Alternatives to animal testing.*
- Sec. 502. Safer disposal of opioids.*
- Sec. 503. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.*
- Sec. 504. Improvements to the Purple Book.*
- Sec. 505. Therapeutic equivalence evaluations.*
- Sec. 506. Modernizing accelerated approval.*
- Sec. 507. Rare disease pilot program.*
- Sec. 508. Supporting review and development of drugs to treat rare diseases.*
- Sec. 509. Generic drug labeling changes.*
- Sec. 510. Limitations on exclusive approval or licensure of orphan drugs.*
- Sec. 511. Ensuring timely access to generics.*
- Sec. 512. Increasing transparency in generic drug applications.*
- Sec. 513. GAO report on nonprofit pharmaceutical organizations.*
- Sec. 514. FDA public meeting on nonprofit prescription drug manufacturers.*
- Sec. 515. 180-day exclusivity period.*

TITLE VI—OTHER REAUTHORIZATIONS

- Sec. 601. Reauthorization of the critical path public-private partnership.*
- Sec. 602. Reauthorization of the best pharmaceuticals for children program.*
- Sec. 603. Reauthorization of the humanitarian device exemption incentive.*
- Sec. 604. Reauthorization of the pediatric device consortia program.*
- Sec. 605. Reauthorization of provision pertaining to drugs containing single enantiomers.*
- Sec. 606. Reauthorization of orphan drug grants.*
- Sec. 607. Reauthorization of certain device inspections.*

TITLE VII—ENHANCING FDA HIRING AUTHORITIES

- Sec. 701. Enhancing FDA hiring authority for scientific, technical, and professional personnel.*
- Sec. 702. Strategic workforce plan and report.*

*TITLE VIII—ADVANCING REGULATION OF COSMETICS, DIETARY
SUPPLEMENTS, AND IN VITRO CLINICAL TESTS*

Subtitle A—Cosmetics

- Sec. 801. Short title.*
- Sec. 802. Amendments to cosmetic requirements.*
- Sec. 803. Enforcement and conforming amendments.*
- Sec. 804. Records inspection.*
- Sec. 805. Talc-containing cosmetics.*
- Sec. 806. PFAS in cosmetics.*
- Sec. 807. Sense of the Senate on animal testing.*
- Sec. 808. Funding.*

Subtitle B—Dietary Supplements

- Sec. 811. Regulation of dietary supplements.*

Subtitle C—In Vitro Clinical Tests

- Sec. 821. Short title.*
- Sec. 822. Definitions.*
- Sec. 823. Regulation of in vitro clinical tests.*
- Sec. 824. Enforcement and other provisions.*
- Sec. 825. Transition.*
- Sec. 826. Emergency use authorization.*
- Sec. 827. Antimicrobial susceptibility tests.*
- Sec. 828. Combination products.*
- Sec. 829. Resources.*
- Sec. 830. Authorization of appropriations.*
- Sec. 831. Guidance on Diagnostic Innovation.*
- Sec. 832. GAO report on unique considerations.*

TITLE IX—OTHER PROVISIONS

- Sec. 901. Facilities management.*
- Sec. 902. User fee program transparency and accountability.*
- Sec. 903. OTC hearing aids final rule.*
- Sec. 904. Enhancing coordination and transparency on inspections.*
- Sec. 905. Certificates to foreign governments.*
- Sec. 906. Importation of drugs.*
- Sec. 907. Improving information technology systems of the Food and Drug Administration.*
- Sec. 908. Regulation of certain products as drugs.*
- Sec. 909. Reporting on mailroom and Office of the Executive Secretariat of the Food and Drug Administration.*
- Sec. 910. Protecting infants and improving formula supply.*
- Sec. 911. Predetermined change control plans for devices.*
- Sec. 912. Prohibition against food packaging containing intentionally added PFAS.*
- Sec. 913. Requirements regarding conflicts of interest.*
- Sec. 914. Third party data transparency.*
- Sec. 915. Banned devices.*
- Sec. 916. Medical device cybersecurity.*
- Sec. 917. Women’s Health Research Roadmap.*
- Sec. 918. GAO report on deaths due to the cost of drugs in the United States.*

1 ***TITLE I—FEES RELATING TO***
2 ***DRUGS***

3 ***SEC. 101. SHORT TITLE; FINDING.***

4 (a) *SHORT TITLE.*—*This title may be cited as the*
5 *“Prescription Drug User Fee Amendments of 2022”.*

6 (b) *FINDING.*—*Congress finds that the fees authorized*
7 *by the amendments made in this title will be dedicated to-*
8 *ward expediting the drug development process and the proc-*
9 *ess for the review of human drug applications, including*
10 *postmarket drug safety activities, as set forth in the goals*
11 *identified for purposes of part 2 of subchapter C of chapter*
12 *VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
13 *379g et seq.), in the letters from the Secretary of Health*
14 *and Human Services to the Chairman of the Committee on*
15 *Health, Education, Labor, and Pensions of the Senate and*
16 *the Chairman of the Committee on Energy and Commerce*
17 *of the House of Representatives, as set forth in the Congres-*
18 *sional Record.*

19 ***SEC. 102. DEFINITIONS.***

20 *Section 735 of the Federal Food, Drug, and Cosmetic*
21 *Act (21 U.S.C. 379g) is amended—*

22 (1) *in paragraph (1), in the matter following*
23 *subparagraph (B), by striking “an allergenic extract*
24 *product, or” and inserting “does not include an ap-*
25 *plication with respect to an allergenic extract product*

1 *licensed before October 1, 2022, does not include an*
2 *application with respect to a standardized allergenic*
3 *extract product submitted pursuant to a notification*
4 *to the applicant from the Secretary regarding the ex-*
5 *istence of a potency test that measures the allergenic*
6 *activity of an allergenic extract product licensed by*
7 *the applicant before October 1, 2022, does not include*
8 *an application with respect to”;*

9 *(2) in paragraph (3), in the matter following*
10 *subparagraph (C)—*

11 *(A) by inserting “licensed before October 1,*
12 *2022, a standardized allergenic extract product*
13 *submitted pursuant to a notification to the ap-*
14 *plicant from the Secretary regarding the exist-*
15 *ence of a potency test that measures the aller-*
16 *genic activity of an allergenic extract product li-*
17 *censed by the applicant before October 1, 2022,”*
18 *after “an allergenic extract product”; and*

19 *(B) by adding at the end the following: “If*
20 *a written request to place a product in the dis-*
21 *continued section of either of the lists described*
22 *in subparagraph (C) is submitted to the Sec-*
23 *retary on behalf of an applicant, and the request*
24 *identifies the date the product is, or will be,*
25 *withdrawn from sale, then, for purposes of as-*

1 *sessing the prescription drug program fee under*
 2 *section 736(a)(2), the Secretary shall consider*
 3 *such product to have been included in the discon-*
 4 *tinued section on the later of (i) the date such re-*
 5 *quest was received, or (ii) if the product will be*
 6 *withdrawn from sale on a future date, such fu-*
 7 *ture date when the product is withdrawn from*
 8 *sale. For purposes of subparagraph (C), a prod-*
 9 *uct shall be considered withdrawn from sale once*
 10 *the applicant has ceased its own distribution of*
 11 *the product, whether or not the applicant has or-*
 12 *dered recall of all previously distributed lots of*
 13 *the product, except that a routine, temporary*
 14 *interruption in supply shall not render a prod-*
 15 *uct withdrawn from sale.”; and*

16 *(3) by adding at the end the following:*

17 *“(12) The term ‘skin-test diagnostic product’—*

18 *“(A) means a product—*

19 *“(i) for prick, scratch, intradermal, or*
 20 *subcutaneous administration;*

21 *“(ii) expected to produce a limited,*
 22 *local reaction at the site of administration*
 23 *(if positive), rather than a systemic effect;*

24 *“(iii) not intended to be a preventive*
 25 *or therapeutic intervention; and*

1 “(iv) intended to detect an immediate
2 or delayed-type skin hypersensitivity reac-
3 tion to aid in the diagnosis of—

4 “(I) an allergy to an anti-
5 microbial agent;

6 “(II) an allergy that is not to an
7 antimicrobial agent, if the diagnostic
8 product was authorized for marketing
9 prior to October 1, 2022; or

10 “(III) infection with fungal or
11 mycobacterial pathogens; and

12 “(B) includes positive and negative controls
13 required to interpret the results of a product de-
14 scribed in subparagraph (A).”.

15 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

16 (a) *TYPES OF FEES.*—Section 736(a) of the Federal
17 *Food, Drug, and Cosmetic Act* (21 U.S.C. 379h(a)) is
18 amended—

19 (1) in the matter preceding paragraph (1), by
20 striking “2018” and inserting “2023”;

21 (2) in paragraph (1)—

22 (A) in subparagraph (A), by striking “sub-
23 section (c)(5)” each place it appears and insert-
24 ing “subsection (c)(6)”;

1 (B) in subparagraph (C), by inserting
 2 “prior to approval” after “or was withdrawn”;
 3 and

4 (C) by adding at the end the following:

5 “(H) *EXCEPTION FOR SKIN-TEST DIAG-*
 6 *NOSTIC PRODUCTS.—A human drug application*
 7 *for a skin-test diagnostic product shall not be*
 8 *subject to a fee under subparagraph (A).”; and*
 9 (3) in paragraph (2)—

10 (A) in subparagraph (A)—

11 (i) by striking “subsection (c)(5)” and
 12 inserting “subsection (c)(6)”;

13 (ii) by striking “Except as provided”
 14 and inserting the following:

15 “(i) *PAYMENT OF FEES.—Except as*
 16 *provided”; and*

17 (iii) by adding at the end the fol-
 18 lowing:

19 “(ii) *PREVIOUSLY DISCONTINUED*
 20 *DRUG PRODUCTS.—If a drug product that*
 21 *is identified in a human drug application*
 22 *approved as of October 1 of a fiscal year is*
 23 *not a prescription drug product as of that*
 24 *date because the drug product is in the dis-*
 25 *continued section of a list identified in sec-*

tion 735(3), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each product for a fiscal year in which the fee is payable.”; and

(B) by amending subparagraph (B) to read as follows:

“(B) *EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.*—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

“(i) a large volume parenteral product (a sterile aqueous drug product packaged in

1 *a single-dose container with a volume great-*
 2 *er than or equal to 100 mL, not including*
 3 *powders for reconstitution or pharmacy*
 4 *bulk packages) identified on the list com-*
 5 *plied under section 505(j)(7);*

6 *“(ii) pharmaceutically equivalent (as*
 7 *defined in section 314.3 of title 21, Code of*
 8 *Federal Regulations (or any successor regu-*
 9 *lations)), to another product on the list of*
 10 *products compiled under section 505(j)(7)*
 11 *(not including the discontinued section of*
 12 *such list); or*

13 *“(iii) a skin-test diagnostic product.”.*

14 *(b) FEE REVENUE AMOUNTS.—Section 736(b) of the*
 15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b))*
 16 *is amended—*

17 *(1) in paragraph (1)—*

18 *(A) in the matter preceding subparagraph*
 19 *(A), by striking “2018 through 2022” and insert-*
 20 *ing “2023 through 2027”;*

21 *(B) by redesignating subparagraphs (C)*
 22 *through (F) as subparagraphs (D) through (G),*
 23 *respectively;*

24 *(C) by inserting after subparagraph (B) the*
 25 *following:*

1 “(C) *The dollar amount equal to the stra-*
 2 *tegic hiring and retention adjustment for the fis-*
 3 *cal year (as determined under subsection*
 4 *(c)(2));”;*

5 (D) *in subparagraph (D), as so redesign-*
 6 *ated, by striking “(c)(2)” and inserting*
 7 *“(c)(3)”;*

8 (E) *in subparagraph (E), as so redesign-*
 9 *ated, by striking “(c)(3)” and inserting*
 10 *“(c)(4)”;*

11 (F) *in subparagraph (F), as so redesign-*
 12 *ated, by striking “(c)(4)” and inserting*
 13 *“(c)(5)”;* *and*

14 (G) *in subparagraph (G), as so redesign-*
 15 *ated, by striking clauses (i) through (v) and in-*
 16 *serting the following:*

17 “(i) \$65,773,693 for fiscal year 2023.

18 “(ii) \$25,097,671 for fiscal year 2024.

19 “(iii) \$14,154,169 for fiscal year 2025.

20 “(iv) \$4,864,860 for fiscal year 2026.

21 “(v) \$1,314,620 for fiscal year 2027.”;

22 *and*

23 (2) *in paragraph (3)—*

1 (A) in subparagraph (A), by striking
 2 “2018, \$878,590,000” and inserting “2023,
 3 \$1,151,522,958”; and

4 (B) in subparagraph (B)—

5 (i) by striking “2019 through 2022”
 6 and inserting “2024 through 2027”; and

7 (ii) by striking “subsection (c)(3) or
 8 (c)(4)” and inserting “subsection (c)(4) or
 9 (c)(5)”.

10 (c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—Section
 11 736(c) of the Federal Food, Drug, and Cosmetic Act (21
 12 U.S.C. 379h(c)) is amended—

13 (1) in paragraph (1)(B)(ii), by striking “Wash-
 14 ington-Baltimore, DC–MD–VA–WV” and inserting
 15 “Washington–Arlington–Alexandria, DC–VA–MD–
 16 WV”;

17 (2) by redesignating paragraphs (2) through (6)
 18 as paragraphs (3) through (7), respectively;

19 (3) by inserting after paragraph (1) the fol-
 20 lowing:

21 “(2) *STRATEGIC HIRING AND RETENTION AD-*
 22 *JUSTMENT.*—For each fiscal year, after the annual
 23 base revenue established in subsection (b)(1)(A) is ad-
 24 justed for inflation in accordance with paragraph (1),

1 *the Secretary shall further increase the fee revenue*
 2 *and fees—*

3 “(A) for fiscal year 2023, by \$9,000,000;

4 *and*

5 “(B) for fiscal year 2024 and each subse-
 6 quent fiscal year, by \$4,000,000.”;

7 (4) in paragraph (3), as so redesignated—

8 (A) in subparagraph (A)—

9 (i) by striking “for inflation”; and

10 (ii) by striking “paragraph (1)” and
 11 inserting “paragraphs (1) and (2)”;

12 (B) by amending subparagraph (B) to read
 13 as follows:

14 “(B) *METHODOLOGY.*—For purposes of this
 15 paragraph, the Secretary shall employ the capac-
 16 ity planning methodology utilized by the Sec-
 17 retary in setting fees for fiscal year 2021, as de-
 18 scribed in the notice titled ‘Prescription Drug
 19 User Fee Rates for Fiscal Year 2021’ (85 Fed.
 20 Reg. 46651; August 3, 2020). The workload cat-
 21 egories used in forecasting shall include only the
 22 activities described in such notice and, as fea-
 23 sible, additional activities that are directly re-
 24 lated to the direct review of applications and
 25 supplements, including additional formal meet-

ing types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in forecasting any non-core review activities, including any activities that the Secretary referenced for potential future use in such notice but did not utilize in the setting fees for fiscal year 2021.”;

(C) by striking subparagraph (C);

(D) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively;

(E) in subparagraph (C), as so redesignated—

(i) by striking “year) and” and inserting “year),”; and

(ii) by striking the period and inserting “, and subsection (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).”; and

1 (F) in subparagraph (D), as so redesign-
2 nated, by striking “paragraph (5)” and insert-
3 ing “paragraph (6)”;

4 (5) in paragraph (4), as so redesignated—

5 (A) by amending subparagraph (A) to read
6 as follows:

7 “(A) INCREASE.—For fiscal year 2023 and
8 subsequent fiscal years, the Secretary shall, in
9 addition to adjustments under paragraphs (1),
10 (2), and (3), further increase the fee revenue and
11 fees if such an adjustment is necessary to provide
12 for at least the following amounts of operating
13 reserves of carryover user fees for the process for
14 the review of human drug applications for each
15 fiscal year, as follows:

16 “(i) For fiscal year 2023, at least 8
17 weeks of operating reserves.

18 “(ii) For fiscal year 2024, at least 9
19 weeks of operating reserves.

20 “(iii) For fiscal year 2025 and subse-
21 quent fiscal years, at least 10 weeks of oper-
22 ating reserves.”; and

23 (B) in subparagraph (C), by striking
24 “paragraph (5)” and inserting “paragraph (6)”;

1 (6) by amending paragraph (5), as so redesign-
 2 nated, to read as follows:

3 “(5) *ADDITIONAL DIRECT COST ADJUSTMENT.*—
 4 *The Secretary shall, in addition to adjustments under*
 5 *paragraphs (1), (2), (3), and (4), further increase the*
 6 *fee revenue and fees—*

7 “(A) for fiscal year 2023, by \$44,386,150;

8 *and*

9 “(B) for fiscal years 2024 through 2027, by
 10 *the amount set forth in clauses (i) through (iv),*
 11 *as applicable, multiplied by the Consumer Price*
 12 *Index for urban consumers (Washington–Arling-*
 13 *ton–Alexandria, DC–VA–MD–WV; Not Season-*
 14 *ally Adjusted; All Items; Annual Index) for the*
 15 *most recent year of available data, divided by*
 16 *such Index for 2021—*

17 “(i) for fiscal year 2024, \$60,967,993;

18 “(ii) for fiscal year 2025, \$35,799,314;

19 “(iii) for fiscal year 2026, \$35,799,314;

20 *and*

21 “(iv) for fiscal year 2027,

22 \$35,799,314.”; *and*

23 (7) in paragraph (6), as so redesignated, by
 24 striking “2017” and inserting “2022”.

1 (d) *CREDITING AND AVAILABILITY OF FEES.*—Section
 2 736(g)(3) of the *Federal Food, Drug, and Cosmetic Act* (21
 3 U.S.C. 379h(g)(3)) is amended by striking “2018 through
 4 2022” and inserting “2023 through 2027”.

5 (e) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
 6 *AND REFUNDS.*—Section 736(i) of the *Federal Food, Drug,*
 7 *and Cosmetic Act* (21 U.S.C. 379h(i)) is amended to read
 8 as follows:

9 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
 10 *EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING*
 11 *FEES.*—To qualify for consideration for a waiver or reduc-
 12 tion under subsection (d), an exemption under subsection
 13 (k), or the return of any fee paid under this section, includ-
 14 ing if the fee is claimed to have been paid in error, a person
 15 shall submit to the Secretary a written request justifying
 16 such waiver, reduction, exemption, or return not later than
 17 180 days after such fee is due. A request submitted under
 18 this paragraph shall include any legal authorities under
 19 which the request is made.”.

20 (f) *ORPHAN DRUGS.*—Section 736(k) of the *Federal*
 21 *Food, Drug, and Cosmetic Act* (21 U.S.C. 379h(k)) is
 22 amended—

23 (1) in paragraph (1)(B), by striking “during the
 24 previous year” and inserting “, as determined under
 25 paragraph (2)”; and

1 (2) in paragraph (2), by striking “that its gross
 2 annual revenues” and all that follows through the pe-
 3 riod at the end and inserting “supported by tax re-
 4 turns submitted to the Internal Revenue Service, or,
 5 as necessary, by other appropriate financial informa-
 6 tion, that its gross annual revenues did not exceed
 7 \$50,000,000 for the last calendar year ending prior to
 8 the fiscal year for which the exemption is requested.”.

9 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.**

10 Section 736B of the Federal Food, Drug, and Cosmetic
 11 Act (21 U.S.C. 379h–2) is amended—

12 (1) by striking “2018” each place it appears and
 13 inserting “2023”;

14 (2) by striking “Prescription Drug User Fee
 15 Amendments of 2017” each place it appears and in-
 16 serting “Prescription Drug User Fee Amendments of
 17 2022”;

18 (3) in subsection (a)(4), by striking “2020” and
 19 inserting “2023”; and

20 (4) in subsection (f), by striking “2022” each
 21 place it appears and inserting “2027”.

22 **SEC. 105. SUNSET DATES.**

23 (a) *AUTHORIZATION.*—Sections 735 and 736 of the
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
 25 379h) shall cease to be effective October 1, 2027.

1 (b) *REPORTING REQUIREMENTS.*—Section 736B of the
 2 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379h–
 3 2) shall cease to be effective January 31, 2028.

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
 5 1, 2022, subsections (a) and (b) of section 104 of the *FDA*
 6 *Reauthorization Act of 2017* (Public Law 115–52) are re-
 7 pealed.

8 **SEC. 106. EFFECTIVE DATE.**

9 *The amendments made by this title shall take effect*
 10 *on October 1, 2022, or the date of the enactment of this*
 11 *Act, whichever is later, except that fees under part 2 of sub-*
 12 *chapter C of chapter VII of the Federal Food, Drug, and*
 13 *Cosmetic Act (21 U.S.C. 379g et seq.) shall be assessed for*
 14 *all human drug applications received on or after October*
 15 *1, 2022, regardless of the date of the enactment of this Act.*

16 **SEC. 107. SAVINGS CLAUSE.**

17 *Notwithstanding the amendments made by this title,*
 18 *part 2 of subchapter C of chapter VII of the Federal Food,*
 19 *Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in effect*
 20 *on the day before the date of the enactment of this title,*
 21 *shall continue to be in effect with respect to human drug*
 22 *applications and supplements (as defined in such part as*
 23 *of such day) that were accepted by the Food and Drug Ad-*
 24 *ministration for filing on or after October 1, 2017, but be-*
 25 *fore October 1, 2022, with respect to assessing and collecting*

1 *any fee required by such part for a fiscal year prior to fiscal*
 2 *year 2023.*

3 ***TITLE II—FEES RELATING TO***
 4 ***DEVICES***

5 ***SEC. 201. SHORT TITLE; FINDING.***

6 (a) *SHORT TITLE.*—*This title may be cited as the*
 7 *“Medical Device User Fee Amendments of 2022”.*

8 (b) *FINDING.*—*Congress finds that the fees authorized*
 9 *under the amendments made by this title will be dedicated*
 10 *toward expediting the process for the review of device appli-*
 11 *cations and for assuring the safety and effectiveness of de-*
 12 *vices, as set forth in the goals identified for purposes of part*
 13 *3 of subchapter C of chapter VII of the Federal Food, Drug,*
 14 *and Cosmetic Act in the letters from the Secretary of Health*
 15 *and Human Services to the Chairman of the Committee on*
 16 *Health, Education, Labor, and Pensions of the Senate and*
 17 *the Chairman of the Committee on Energy and Commerce*
 18 *of the House of Representatives, as set forth in the Congres-*
 19 *sional Record.*

20 ***SEC. 202. DEFINITIONS.***

21 *Section 737 of the Federal Food, Drug, and Cosmetic*
 22 *Act (21 U.S.C. 379i) is amended—*

23 (1) *in paragraph (9)—*

24 (A) *in the matter preceding subparagraph*

25 (A), *by striking “and premarket notification*

1 *submissions” and inserting “premarket notifica-*
 2 *tion submissions, and de novo classification re-*
 3 *quests”;*

4 *(B) in subparagraph (D), by striking “and*
 5 *submissions” and inserting “submissions, and de*
 6 *novo classification requests”;*

7 *(C) in subparagraph (F), by striking “and*
 8 *premarket notification submissions” and insert-*
 9 *ing “premarket notification submissions, and de*
 10 *novo classification requests”;*

11 *(D) in subparagraphs (G) and (H), by*
 12 *striking “or submissions” each place it appears*
 13 *and inserting “submissions, or requests”; and*

14 *(E) in subparagraph (K), by striking “or*
 15 *premarket notification submissions” and insert-*
 16 *ing “premarket notification submissions, or de*
 17 *novo classification requests”; and*

18 *(2) in paragraph (11), by striking “2016” and*
 19 *inserting “2021”.*

20 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

21 *(a) TYPES OF FEES.—Section 738(a) of the Federal*
 22 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is*
 23 *amended—*

24 *(1) in paragraph (1), by striking “2018” and in-*
 25 *serting “2023”; and*

1 (2) *in paragraph (2)—*

2 (A) *in subparagraph (A)—*

3 (i) *in the matter preceding clause (i),*
4 *by striking “2017” and inserting “2022”;*

5 (ii) *in clause (iii), by striking “75 per-*
6 *cent” and inserting “80 percent”; and*

7 (iii) *in clause (viii), by striking “3.4*
8 *percent” and inserting “4.5 percent”;*

9 (B) *in subparagraph (B)(iii), by striking*
10 *“or premarket notification submission” and in-*
11 *serting “premarket notification submission, or de*
12 *novo classification request”; and*

13 (C) *in subparagraph (C), by striking “or*
14 *periodic reporting concerning a class III device”*
15 *and inserting “periodic reporting concerning a*
16 *class III device, or de novo classification re-*
17 *quest”.*

18 (b) *FEE AMOUNTS.—Section 738(b) of the Federal*
19 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is*
20 *amended—*

21 (1) *in paragraph (1), by striking “2018 through*
22 *2022” and inserting “2023 through 2027”;*

23 (2) *by amending the table in paragraph (2) to*
24 *read as follows:*

<i>“Fee Type</i>	<i>Fiscal Year 2023</i>	<i>Fiscal Year 2024</i>	<i>Fiscal Year 2025</i>	<i>Fiscal Year 2026</i>	<i>Fiscal Year 2027</i>
<i>Premarket Applica- tion</i>	\$425,000	\$435,000	\$445,000	\$455,000	\$470,000
<i>Establishment Reg- istration</i>	\$6,250	\$6,875	\$7,100	\$7,575	\$8,465”;

1 *and*

2 *(3) in paragraph (3), by amending subpara-*
3 *graphs (A) through (E) to read as follows:*

4 *“(A) \$312,606,000 for fiscal year 2023.*

5 *“(B) \$335,750,000 for fiscal year 2024.*

6 *“(C) \$350,746,400 for fiscal year 2025.*

7 *“(D) \$366,486,300 for fiscal year 2026.*

8 *“(E) \$418,343,000 for fiscal year 2027.”.*

9 *(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section*
10 *738(c) of the Federal Food, Drug, and Cosmetic Act (21*
11 *U.S.C. 379j(c)) is amended—*

12 *(1) in paragraph (1), by striking “2017” and in-*
13 *serting “2022”;*

14 *(2) in paragraph (2)—*

15 *(A) by striking “2018” each place it ap-*
16 *pears and inserting “2023”;*

17 *(B) in subparagraph (B)(ii), by striking*
18 *“2016” and inserting “2022”;*

19 *(C) in subparagraph (C)(i)(II), by striking*
20 *“Washington-Baltimore, DC–MD–VA–WV” and*

1 inserting “Washington–Arlington–Alexandria,
2 DC–VA–MD–WV”; and

3 (D) in subparagraph (D), by striking
4 “2022” and inserting “2027”;

5 (3) in paragraph (3), by striking “2018 through
6 2022” and inserting “2023 through 2027”;

7 (4) by redesignating paragraphs (4) and (5) as
8 paragraphs (7) and (8), respectively; and

9 (5) by inserting after paragraph (3) the fol-
10 lowing:

11 “(4) *PERFORMANCE IMPROVEMENT ADJUST-*
12 *MENT.*—

13 “(A) *IN GENERAL.*—For each of fiscal years
14 2025 through 2027, after the adjustment under
15 paragraph (3), the base establishment registra-
16 tion fee amounts for such fiscal year shall be in-
17 creased to reflect changes in the resource needs of
18 the Secretary due to improved review perform-
19 ance goals for the process for the review of device
20 applications identified in the letters described in
21 section 201(b) of the Medical Device User Fee
22 Amendments of 2022, as the Secretary deter-
23 mines necessary to achieve an increase in total
24 fee collections for such fiscal year, equal to the
25 following amounts, as applicable:

1 “(i) For fiscal year 2025, the product
2 of—

3 “(I) the amount determined under
4 subparagraph (B)(i)(I); and

5 “(II) the applicable inflation ad-
6 justment under paragraph (2)(B) for
7 such fiscal year.

8 “(ii) For fiscal year 2026, the product
9 of—

10 “(I) the sum of the amounts deter-
11 mined under subparagraphs (B)(i)(II),
12 (B)(ii)(I), and (B)(iii)(I); and

13 “(II) the applicable inflation ad-
14 justment under paragraph (2)(B) for
15 such fiscal year.

16 “(iii) For fiscal year 2027, the product
17 of—

18 “(I) the sum of the amounts deter-
19 mined under subparagraphs
20 (B)(i)(III), (B)(ii)(II), and
21 (B)(iii)(II); and

22 “(II) the applicable inflation ad-
23 justment under paragraph (2)(B) for
24 such fiscal year.

25 “(B) AMOUNTS.—

1 “(i) *PRESUBMISSION AMOUNT.—For*
2 *purposes of subparagraph (A), with respect*
3 *to the presubmission written feedback goal,*
4 *the amounts determined under this sub-*
5 *paragraph are as follows:*

6 “(I) *For fiscal year 2025,*
7 *\$15,396,600 if the goal for fiscal year*
8 *2023 is met.*

9 “(II) *For fiscal year 2026—*

10 “(aa) *\$15,396,600 if the goal*
11 *for fiscal year 2023 is met and*
12 *the goal for fiscal year 2024 is*
13 *missed; or*

14 “(bb) *\$36,792,200 if the goal*
15 *for fiscal year 2024 is met.*

16 “(III) *For fiscal year 2027—*

17 “(aa) *\$15,396,600 if the goal*
18 *for fiscal year 2023 is met and*
19 *the goal for each of fiscal years*
20 *2024 and 2025 is missed;*

21 “(bb) *\$36,792,200 if the goal*
22 *for fiscal year 2024 is met and*
23 *the goal for fiscal year 2025 is*
24 *missed; or*

1 “(cc) \$40,572,600 if the goal
2 for fiscal year 2025 is met.

3 “(ii) *DE NOVO CLASSIFICATION RE-*
4 *QUEST AMOUNT.*—For purposes of subpara-
5 graph (A), with respect to the de novo deci-
6 sion goal, the amounts determined under
7 this subparagraph are as follows:

8 “(I) For fiscal year 2026,
9 \$6,323,500 if the goal for fiscal year
10 2023 is met.

11 “(II) For fiscal year 2027—

12 “(aa) \$6,323,500 if the goal
13 for fiscal year 2023 is met and
14 the goal for fiscal year 2024 is
15 missed; or

16 “(bb) \$11,765,400 if the goal
17 for fiscal year 2024 is met.

18 “(iii) *PREMARKET NOTIFICATION AND*
19 *PREMARKET APPROVAL AMOUNT.*—For pur-
20 poses of subparagraph (A), with respect to
21 the 510(k) decision goal, 510(k) shared out-
22 come total time to decision goal, PMA deci-
23 sion goal, and PMA shared outcome total
24 time to decision goal, the amounts deter-

1 *mined under this subparagraph are as fol-*
 2 *lows:*

3 *“(I) For fiscal year 2026,*
 4 *\$1,020,000 if the 4 goals for fiscal year*
 5 *2023 are met.*

6 *“(II) For fiscal year 2027—*

7 *“(aa) \$1,020,000 if the 4*
 8 *goals for fiscal year 2023 are met*
 9 *and one or more of the 4 goals for*
 10 *fiscal year 2024 is missed; or*

11 *“(bb) \$3,906,000 if the 4*
 12 *goals for fiscal year 2024 are met.*

13 *“(C) PERFORMANCE CALCULATION.—For*
 14 *purposes of this paragraph, performance of the*
 15 *following goals shall be determined as specified*
 16 *in the letters described in section 201(b) of the*
 17 *Medical Device User Fee Amendments of 2022*
 18 *and based on data available as of the applicable*
 19 *dates as follows:*

20 *“(i) The performance of the pre-*
 21 *submission written feedback goal—*

22 *“(I) for fiscal year 2023, shall be*
 23 *based on data available as of March*
 24 *31, 2024;*

1 “(II) for fiscal year 2024, shall be
2 based on data available as of March
3 31, 2025; and

4 “(III) for fiscal year 2025, shall
5 be based on data available as of March
6 31, 2026.

7 “(ii) The performance of the de novo
8 decision goal, 510(k) decision goal, 510(k)
9 shared outcome total time to decision goal,
10 PMA decision goal, and PMA shared out-
11 come total time to decision goal—

12 “(I) for fiscal year 2023, shall be
13 based on data available as of March
14 31, 2025; and

15 “(II) for fiscal year 2024, shall be
16 based on data available as of March
17 31, 2026.

18 “(D) DEFINITIONS.—For purposes of this
19 paragraph, the terms ‘presubmission written
20 feedback goal’, ‘de novo decision goal’, ‘510(k) de-
21 cision goal’, ‘510(k) shared outcome total time to
22 decision goal’, ‘PMA decision goal’, and ‘PMA
23 shared outcome total time to decision goal’ have
24 the meanings given such terms in the goals iden-
25 tified in the letters described in section 201(b) of

1 *the Medical Device User Fee Amendments of*
2 *2022.*

3 “(5) *HIRING ADJUSTMENT.*—

4 “(A) *IN GENERAL.*—For each of fiscal years
5 *2025 through 2027, after the adjustments under*
6 *paragraphs (3) and (4), if applicable, the base*
7 *establishment registration fee amounts shall be*
8 *decreased as the Secretary determines necessary*
9 *to achieve a reduction in total fee collections*
10 *equal to the hiring adjustment amount under*
11 *subparagraph (B), if the number of hires to sup-*
12 *port the process for the review of device applica-*
13 *tions falls below the following thresholds for the*
14 *applicable fiscal years:*

15 “(i) *For fiscal year 2025, 85 percent of*
16 *the hiring goal specified in subparagraph*
17 *(C) for fiscal year 2023.*

18 “(ii) *For fiscal year 2026, 90 percent*
19 *of the hiring goal specified in subparagraph*
20 *(C) for fiscal year 2024.*

21 “(iii) *For fiscal year 2027, 90 percent*
22 *of the hiring goal specified in subparagraph*
23 *(C) for fiscal year 2025.*

24 “(B) *HIRING ADJUSTMENT AMOUNT.*—The
25 *hiring adjustment amount for fiscal year 2025*

1 *and each subsequent fiscal year is the product*
 2 *of—*

3 “(i) *the number of hires by which the*
 4 *hiring goal specified in subparagraph (C)*
 5 *for the fiscal year before the prior fiscal*
 6 *year was missed;*

7 “(ii) *\$72,877; and*

8 “(iii) *the applicable inflation adjust-*
 9 *ment under paragraph (2)(B) for the fiscal*
 10 *year for which the hiring goal was missed.*

11 “(C) *HIRING GOALS.—*

12 “(i) *IN GENERAL.—For purposes of*
 13 *subparagraph (B), the hiring goals for each*
 14 *of fiscal years 2023 through 2025 are as fol-*
 15 *lows:*

16 “(I) *For fiscal year 2023, 144*
 17 *hires.*

18 “(II) *For fiscal year 2024, 42*
 19 *hires.*

20 “(III) *For fiscal year 2025—*

21 “(aa) *24 hires if the base es-*
 22 *tablishment registration fees are*
 23 *not increased by the amount de-*
 24 *termined under paragraph*
 25 *(4)(A)(i); or*

1 “(bb) 83 hires if the base es-
2 tablishment registration fees are
3 increased by the amount deter-
4 mined under paragraph (4)(A)(i).

5 “(ii) NUMBER OF HIRES.—For pur-
6 poses of this paragraph, the number of hires
7 for a fiscal year shall be determined by the
8 Secretary, as set forth in the letters de-
9 scribed in section 201(b) of the Medical De-
10 vice User Fee Amendments of 2022.

11 “(6) OPERATING RESERVE ADJUSTMENT.—

12 “(A) IN GENERAL.—For each of fiscal years
13 2023 through 2027, after the adjustments under
14 paragraphs (3), (4), and (5), if applicable, if the
15 Secretary has operating reserves of carryover
16 user fees for the process for the review of device
17 applications in excess of the designated amount
18 in subparagraph (B), the Secretary shall de-
19 crease the base establishment registration fee
20 amounts to provide for not more than such des-
21 ignated amount of operating reserves.

22 “(B) DESIGNATED AMOUNT.—Subject to
23 subparagraph (C), for each fiscal year, the des-
24 ignated amount in this subparagraph is equal to
25 the sum of—

1 “(i) 13 weeks of operating reserves of
2 carryover user fees; and

3 “(ii) the 1 month of operating reserves
4 described in paragraph (8).

5 “(C) *EXCLUDED AMOUNT*.—For the period
6 of fiscal years 2023 through 2026, a total
7 amount equal to \$118,000,000 shall not be con-
8 sidered part of the designated amount under sub-
9 paragraph (B) and shall not be subject to the de-
10 crease under subparagraph (A).”.

11 (d) *SMALL BUSINESSES*.—Section 738 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
13 ed—

14 (1) in subsection (a)(3)(B)—

15 (A) by striking “No fee” and inserting the
16 following:

17 “(i) *IN GENERAL*.—No fee”; and

18 (B) by adding at the end the following:

19 “(ii) *SMALL BUSINESSES FEE WAIV-*
20 *ER*.—

21 “(I) *DEFINITION OF SMALL BUSI-*
22 *NESS*.—For the purposes of this clause,
23 the term ‘small business’ means an en-
24 tity that reported \$1,000,000 or less of
25 gross receipts or sales in its most re-

1 *cent Federal income tax return for a*
2 *taxable year, including such returns of*
3 *all of its affiliates.*

4 “(II) *WAIVER.—The Secretary*
5 *may grant a waiver of the fee required*
6 *under subparagraph (A) for the annual*
7 *registration (excluding the initial reg-*
8 *istration) of an establishment for a*
9 *year, if the Secretary finds that the es-*
10 *tablishment is a small business and*
11 *paying the fee for such year represents*
12 *a financial hardship to the establish-*
13 *ment as determined on the basis of cri-*
14 *teria established by the Secretary.*

15 “(III) *FIRMS SUBMITTING TAX*
16 *RETURNS TO THE UNITED STATES IN-*
17 *TERNAL REVENUE SERVICE.—The es-*
18 *tablishment shall support its claim*
19 *that it meets the definition under sub-*
20 *clause (I) by submission of a copy of*
21 *its most recent Federal income tax re-*
22 *turn for a taxable year, and a copy of*
23 *such returns of its affiliates, which*
24 *show an amount of gross sales or re-*
25 *ceipts that is less than the maximum*

1 *established in subclause (I). The estab-*
2 *lishment, and each of such affiliates,*
3 *shall certify that the information pro-*
4 *vided is a true and accurate copy of*
5 *the actual tax forms they submitted to*
6 *the Internal Revenue Service. If no tax*
7 *forms are submitted for any affiliate,*
8 *the establishment shall certify that the*
9 *establishment has no affiliates.*

10 “(IV) *FIRMS NOT SUBMITTING*
11 *TAX RETURNS TO THE UNITED STATES*
12 *INTERNAL REVENUE SERVICE.—In the*
13 *case of an establishment that has not*
14 *previously submitted a Federal income*
15 *tax return, the establishment and each*
16 *of its affiliates shall demonstrate that*
17 *it meets the definition under subclause*
18 *(I) by submission of a signed certifi-*
19 *cation, in such form as the Secretary*
20 *may direct through a notice published*
21 *in the Federal Register, that the estab-*
22 *lishment or affiliate meets the criteria*
23 *for a small business and a certifi-*
24 *cation, in English, from the national*
25 *taxing authority, if extant, of the coun-*

1 *try in which the establishment or, if*
2 *applicable, affiliate is headquartered.*
3 *The certification from such taxing au-*
4 *thority shall bear the official seal of*
5 *such taxing authority and shall pro-*
6 *vide the establishment's or affiliate's*
7 *gross receipts or sales for the most re-*
8 *cent year in both the local currency of*
9 *such country and in United States dol-*
10 *lars, the exchange rate used in con-*
11 *verting such local currency to dollars,*
12 *and the dates during which these re-*
13 *ceipts or sales were collected. The estab-*
14 *lishment shall also submit a statement*
15 *signed by the head of the establish-*
16 *ment's firm or by its chief financial of-*
17 *ficer that the establishment has sub-*
18 *mitted certifications for all of its affili-*
19 *ates, or that the establishment has no*
20 *affiliates.*

21 *“(V) REQUEST FOR WAIVER.—An*
22 *establishment seeking a fee waiver for a*
23 *year under this clause shall submit*
24 *supporting information to the Sec-*
25 *retary at least 60 days before the fee is*

1 required pursuant to subparagraph
 2 (C). The decision of the Secretary re-
 3 garding whether an entity may receive
 4 the waiver for such year is not review-
 5 able.”;

6 (2) in subsection (d)(2)(B)(iii), by inserting “, if
 7 extant,” after “national taxing authority”; and

8 (3) in subsection (e)(2)(B)(iii), by inserting “, if
 9 extant,” after “national taxing authority”.

10 (e) *CONDITIONS.*—Section 738(g) of the Federal Food,
 11 Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is amended—

12 (1) in paragraph (1)(A), by striking
 13 “\$320,825,000” and inserting “\$398,566,000”; and

14 (2) in paragraph (2), by inserting “de novo clas-
 15 sification requests,” after “class III device,”.

16 (f) *AUTHORIZATION OF APPROPRIATIONS.*—Section
 17 738(h)(3) of the Federal Food, Drug, and Cosmetic Act (21
 18 U.S.C. 379j(h)(3)) is amended to read as follows:

19 “(3) *AUTHORIZATION OF APPROPRIATIONS.*—

20 “(A) *IN GENERAL.*—For each of the fiscal
 21 years 2023 through 2027, there is authorized to
 22 be appropriated for fees under this section an
 23 amount equal to the revenue amount determined
 24 in subparagraph (B), less the amount of reduc-
 25 tions determined in subparagraph (C).

1 “(B) *REVENUE AMOUNT.*—For purposes of
2 this paragraph, the revenue amount for each fis-
3 cal year is the sum of—

4 “(i) the total revenue amount under
5 subsection (b)(3) for the fiscal year, as ad-
6 justed under subsection (c)(2); and

7 “(ii) the performance improvement ad-
8 justment amount for the fiscal year under
9 subsection (c)(4)(A), if applicable.

10 “(C) *AMOUNT OF REDUCTIONS.*—For pur-
11 poses of this paragraph, the amount of reduc-
12 tions for each fiscal year is the sum of—

13 “(i) the hiring adjustment amount for
14 the fiscal year under subsection (c)(5), if
15 applicable; and

16 “(ii) the operating reserve adjustment
17 amount for the fiscal year under subsection
18 (c)(6), if applicable.”.

19 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENT.**

20 (a) *PERFORMANCE REPORTS.*—Section 738A(a) of the
21 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
22 1(a)) is amended—

23 (1) by striking “fiscal year 2018” each place it
24 appears and inserting “fiscal year 2023”; and

1 (2) *by striking “Medical Device User Fee*
 2 *Amendments of 2017” each place it appears and in-*
 3 *serting “Medical Device User Fee Amendments of*
 4 *2022”;*

5 (3) *in paragraph (1)—*

6 (A) *in subparagraph (A), by redesignating*
 7 *the second clause (iv) (relating to analysis) as*
 8 *clause (v); and*

9 (B) *in subparagraph (A)(iv) (relating to ra-*
 10 *tionale for MDUFA program changes), by strik-*
 11 *ing “fiscal year 2020” and inserting “fiscal year*
 12 *2023”;* *and*

13 (4) *in paragraph (4), by striking “2018 through*
 14 *2022” and inserting “2023 through 2027.”*

15 (b) *REAUTHORIZATION.—Section 738A(b) of the Fed-*
 16 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b))*
 17 *is amended—*

18 (1) *in paragraph (1), by striking “2022” and in-*
 19 *serting “2027”;* *and*

20 (2) *in paragraph (5), by striking “2022” and in-*
 21 *serting “2027”.*

22 **SEC. 205. ACCREDITATION PROGRAMS.**

23 (a) *ACCREDITATION SCHEME FOR CONFORMITY AS-*
 24 *SESSMENT.—Section 514(d) of the Federal Food, Drug, and*
 25 *Cosmetic Act (21 U.S.C. 360d(d)) is amended—*

1 (1) *in the subsection heading, by striking*
 2 *“PILOT”;*

3 (2) *in paragraph (1)—*

4 (A) *in the matter preceding subparagraph*
 5 (A), *by striking “pilot”;*

6 (B) *in subparagraph (A)—*

7 (i) *by inserting “meeting criteria spec-*
 8 *ified by the Secretary in guidance” after*
 9 *“testing laboratories”;*

10 (ii) *by inserting “in guidance” after*
 11 *“by the Secretary”; and*

12 (iii) *by striking “assess the conform-*
 13 *ance of a device with” and inserting “con-*
 14 *duct testing to support the assessment of the*
 15 *conformance of a device to”; and*

16 (C) *in subparagraph (B)—*

17 (i) *by striking “determinations” and*
 18 *inserting “results”;*

19 (ii) *by inserting “to support” after “so*
 20 *accredited”; and*

21 (iii) *by striking “a particular such de-*
 22 *termination” and inserting “particular*
 23 *such results”;*

24 (3) *in paragraph (2)—*

1 (A) in the paragraph heading, by striking
2 “DETERMINATIONS” and inserting “RESULTS”;

3 (B) in subparagraph (A)—

4 (i) by striking “determinations by test-
5 ing laboratories” and all that follows
6 through “such determinations or” and in-
7 serting “results by testing laboratories ac-
8 credited pursuant to this subsection, includ-
9 ing by conducting periodic audits of such
10 results or of the”;

11 (ii) by inserting a comma after “or
12 testing laboratories”;

13 (iii) by inserting “or recognition of an
14 accreditation body” after “accreditation of
15 such testing laboratory”; and

16 (iv) by striking “such device” and in-
17 serting “a device”; and

18 (C) in subparagraph (B)—

19 (i) by striking “by a testing laboratory
20 so accredited” and inserting “under this
21 subsection”; and

22 (ii) by inserting “or recognition of an
23 accreditation body” before “under para-
24 graph (1)(A)”;

25 (4) in paragraph (3)(C)—

1 (A) in the subparagraph heading, by insert-
2 ing “AND TRANSITION” after “INITIATION”; and

3 (B) by adding at the end the following:
4 “After September 30, 2023, such pilot program
5 will be considered to be completed, and the Sec-
6 retary shall have the authority to continue oper-
7 ating a program consistent with this sub-
8 section.”; and

9 (5) by striking paragraph (4).

10 (b) *ACCREDITED PERSONS*.—Section 523(c) of the
11 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 360m(c))
12 is amended by striking “2022” and inserting “2027”.

13 **SEC. 206. SUNSET DATES.**

14 (a) *AUTHORIZATION*.—Sections 737 and 738 of the
15 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379i;
16 379ff) shall cease to be effective October 1, 2027.

17 (b) *REPORTING REQUIREMENTS*.—Section 738A of the
18 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
19 1) shall cease to be effective January 31, 2028.

20 (c) *PREVIOUS SUNSET PROVISION*.—Effective October
21 1, 2022, subsections (a) and (b) of section 210 of the *FDA*
22 *Reauthorization Act of 2017* (Public Law 115–52) are re-
23 pealed.

1 **SEC. 207. EFFECTIVE DATE.**

2 *The amendments made by this title shall take effect*
 3 *on October 1, 2022, or the date of the enactment of this*
 4 *Act, whichever is later, except that fees under part 3 of sub-*
 5 *chapter C of chapter VII of the Federal Food, Drug, and*
 6 *Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for*
 7 *all submissions listed in section 738(a)(2)(A) of such Act*
 8 *received on or after October 1, 2022, regardless of the date*
 9 *of the enactment of this Act.*

10 **SEC. 208. SAVINGS CLAUSE.**

11 *Notwithstanding the amendments made by this title,*
 12 *part 3 of subchapter C of chapter VII of the Federal Food,*
 13 *Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect*
 14 *on the day before the date of the enactment of this title,*
 15 *shall continue to be in effect with respect to the submissions*
 16 *listed in section 738(a)(2)(A) of such Act (as defined in such*
 17 *part as of such day) that on or after October 1, 2017, but*
 18 *before October 1, 2022, were received by the Food and Drug*
 19 *Administration with respect to assessing and collecting any*
 20 *fee required by such part for a fiscal year prior to fiscal*
 21 *year 2023.*

22 **TITLE III—FEES RELATING TO**
 23 **GENERIC DRUGS**

24 **SEC. 301. SHORT TITLE; FINDING.**

25 *(a) SHORT TITLE.—This title may be cited as the “Ge-*
 26 *neric Drug User Fee Amendments of 2022”.*

1 (b) *FINDING.*—*The Congress finds that the fees author-*
2 *ized by the amendments made in this title will be dedicated*
3 *to human generic drug activities, as set forth in the goals*
4 *identified for purposes of part 7 of subchapter C of chapter*
5 *VII of the Federal Food, Drug, and Cosmetic Act, in the*
6 *letters from the Secretary of Health and Human Services*
7 *to the Chairman of the Committee on Health, Education,*
8 *Labor, and Pensions of the Senate and the Chairman of*
9 *the Committee on Energy and Commerce of the House of*
10 *Representatives, as set forth in the Congressional Record.*

11 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
12 **NERIC DRUG FEES.**

13 (a) *TYPES OF FEES.*—*Section 744B(a) of the Federal*
14 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is*
15 *amended—*

16 (1) *in the matter preceding paragraph (1), by*
17 *striking “2018” and inserting “2023”;*

18 (2) *in paragraph (2)(C), by striking “fiscal*
19 *years 2018 through 2022” and inserting “fiscal years*
20 *2023 through 2027”;*

21 (3) *in paragraph (3)(B), by striking “fiscal*
22 *years 2018 through 2022” and inserting “fiscal years*
23 *2023 through 2027”;*

1 (4) in paragraph (4)(D), by striking “fiscal
2 years 2018 through 2022” and inserting “fiscal years
3 2023 through 2027”; and

4 (5) in paragraph (5)(D), by striking “fiscal
5 years 2018 through 2022” and inserting “fiscal years
6 2023 through 2027”.

7 (b) *FEE REVENUE AMOUNTS*.—Section 744B(b) of the
8 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
9 42(b)) is amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (A)—

12 (i) in the heading, by striking “2018”
13 and inserting “2023”;

14 (ii) by striking “2018” and inserting
15 “2023”; and

16 (iii) by striking “\$493,600,000” and
17 inserting “\$582,500,000”; and

18 (B) in subparagraph (B)—

19 (i) in the heading, by striking “2019
20 THROUGH 2022” and inserting “2024
21 THROUGH 2027”;

22 (ii) by striking “For each” and insert-
23 ing the following:

24 “(i) *IN GENERAL*.—For each”;

1 (iii) by striking “2019 through 2022”
2 and inserting “2024 through 2027”;

3 (iv) by striking “\$493,600,000” and
4 inserting “the base revenue amount under
5 clause (ii)”; and

6 (v) by adding at the end the following:

7 “(ii) *BASE REVENUE AMOUNT.*—The
8 base revenue amount for a fiscal year is the
9 total revenue amount established under this
10 paragraph for the previous fiscal year, not
11 including any adjustments made for such
12 previous fiscal year under subsection
13 (c)(3).”; and

14 (2) in paragraph (2)—

15 (A) in subparagraph (C), by striking “one-
16 third the amount” and inserting “24 percent”;

17 (B) in subparagraph (D), by striking
18 “Seven” and inserting “Six”; and

19 (C) in subparagraph (E)(i), by striking
20 “Thirty-five” and inserting “Thirty-six”.

21 (c) *ADJUSTMENTS.*—Section 744B(c) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is
23 amended—

24 (1) in paragraph (1)—

1 (A) in the matter preceding subparagraph

2 (A)—

3 (i) by striking “2019” and inserting

4 “2024”; and

5 (ii) by striking “the product of the

6 total revenues established in such notice for

7 the prior fiscal year” and inserting “the

8 base revenue amount for the fiscal year de-

9 termined under subsection (b)(1)(B)(ii)”;

10 and

11 (B) in subparagraph (C), by striking

12 “Washington-Baltimore, DC–MD–VA–WV” and

13 inserting “Washington-Arlington-Alexandria,

14 DC–VA–MD–WV”; and

15 (2) by striking paragraph (2) and inserting the

16 following:

17 “(2) CAPACITY PLANNING ADJUSTMENT.—

18 “(A) IN GENERAL.—Beginning with fiscal

19 year 2024, the Secretary shall, in addition to the

20 adjustment under paragraph (1), further in-

21 crease the fee revenue and fees under this section

22 for a fiscal year, in accordance with this para-

23 graph, to reflect changes in the resource capacity

24 needs of the Secretary for human generic drug

25 activities.

1 “(B) *CAPACITY PLANNING METHODOLOGY.*—

2 *The Secretary shall establish a capacity plan-*
3 *ning methodology for purposes of this paragraph,*
4 *which shall—*

5 “(i) *be derived from the methodology*
6 *and recommendations made in the report ti-*
7 *tled ‘Independent Evaluation of the*
8 *GDUFA Resource Capacity Planning Ad-*
9 *justment Methodology: Evaluation and Rec-*
10 *ommendations’ as announced in the Federal*
11 *Register on August 3, 2020 (85 Fed. Reg.*
12 *46658); and*

13 “(ii) *incorporate approaches and at-*
14 *tributes determined appropriate by the Sec-*
15 *retary, including those made in such report*
16 *recommendations, except the workload cat-*
17 *egories used in forecasting resources shall*
18 *only be those specified in section VIII.B.2.e.*
19 *of the letters described in section 301(b) of*
20 *the Generic Drug User Fee Amendments of*
21 *2022.*

22 “(C) *LIMITATIONS.*—

23 “(i) *IN GENERAL.*—*Under no cir-*
24 *cumstances shall an adjustment under this*
25 *paragraph result in fee revenue for a fiscal*

1 *year that is less than the sum of the*
 2 *amounts under subsection (b)(1)(B)(ii) (the*
 3 *base revenue amount for the fiscal year)*
 4 *and paragraph (1) (the dollar amount of*
 5 *the inflation adjustment for the fiscal year).*

6 “(ii) *ADDITIONAL LIMITATION.—An*
 7 *adjustment under this paragraph shall not*
 8 *exceed 3 percent of the sum described in*
 9 *clause (i) for the fiscal year, except that*
 10 *such limitation shall be 4 percent if—*

11 *“(I) for purposes of an adjustment*
 12 *for fiscal year 2024, the Secretary de-*
 13 *termines that, during the period from*
 14 *April 1, 2021, through March 31,*
 15 *2023—*

16 *“(aa) the total number of ab-*
 17 *breivated new drug applications*
 18 *submitted was greater than or*
 19 *equal to 2,000; or*

20 *“(bb) thirty-five percent or*
 21 *more of abbreviated new drug ap-*
 22 *plications submitted related to*
 23 *complex products (as that term is*
 24 *defined in section XI of the letters*
 25 *described in section 301(b) of the*

1 *Generic Drug User Fee Amend-*
2 *ments of 2022);*

3 *“(II) for purposes of an adjust-*
4 *ment for fiscal year 2025, the Sec-*
5 *retary determines that, during the pe-*
6 *riod from April 1, 2022, through*
7 *March 31, 2024—*

8 *“(aa) the total number of ab-*
9 *breivated new drug applications*
10 *submitted was greater than or*
11 *equal to 2,300; or*

12 *“(bb) thirty-five percent or*
13 *more of abbreviated new drug ap-*
14 *plications submitted related to*
15 *complex products (as so defined);*

16 *“(III) for purposes of an adjust-*
17 *ment for fiscal year 2026, the Sec-*
18 *retary determines that, during the pe-*
19 *riod from April 1, 2023, through*
20 *March 31, 2025—*

21 *“(aa) the total number of ab-*
22 *breivated new drug applications*
23 *submitted was greater than or*
24 *equal to 2,300; or*

1 “(bb) *thirty-five percent or*
 2 *more of abbreviated new drug ap-*
 3 *plications submitted related to*
 4 *complex products (as so defined);*
 5 *and*

6 “(IV) *for purposes of an adjust-*
 7 *ment for fiscal year 2027, the Sec-*
 8 *retary determines that, during the pe-*
 9 *riod from April 1, 2024, through*
 10 *March 31, 2026—*

11 “(aa) *the total number of ab-*
 12 *breivated new drug applications*
 13 *submitted was greater than or*
 14 *equal to 2,300; or*

15 “(bb) *thirty-five percent or*
 16 *more of abbreviated new drug ap-*
 17 *plications submitted related to*
 18 *complex products (as so defined).*

19 “(D) *PUBLICATION IN FEDERAL REG-*
 20 *ISTER.—The Secretary shall publish in the Fed-*
 21 *eral Register notice under subsection (a), the fee*
 22 *revenue and fees resulting from the adjustment*
 23 *and the methodology under this paragraph.*

24 “(3) *OPERATING RESERVE ADJUSTMENT.—*

1 “(A) *IN GENERAL.*—For fiscal year 2024
 2 and subsequent fiscal years, the Secretary may,
 3 in addition to adjustments under paragraphs (1)
 4 and (2), further increase the fee revenue and fees
 5 under this section if such an adjustment is nec-
 6 essary to provide operating reserves of carryover
 7 user fees for human generic drug activities for
 8 not more than the number of weeks specified in
 9 subparagraph (B).

10 “(B) *NUMBER OF WEEKS.*—The number of
 11 weeks specified in this subparagraph is—

12 “(i) 8 weeks for fiscal year 2024;

13 “(ii) 9 weeks for fiscal year 2025; and

14 “(iii) 10 weeks for each of fiscal year
 15 2026 and 2027.

16 “(C) *DECREASE.*—If the Secretary has car-
 17 ryover balances for human generic drug activi-
 18 ties in excess of 12 weeks of the operating re-
 19 serves referred to in subparagraph (A), the Sec-
 20 retary shall decrease the fee revenue and fees re-
 21 ferred to in such subparagraph to provide for not
 22 more than 12 weeks of such operating reserves.

23 “(D) *RATIONALE FOR ADJUSTMENT.*—If an
 24 adjustment under this paragraph is made, the
 25 rationale for the amount of the increase or de-

1 crease (as applicable) in fee revenue and fees
 2 shall be contained in the annual Federal Reg-
 3 ister notice under subsection (a) publishing the
 4 fee revenue and fees for the fiscal year involved.”.

5 (d) *ANNUAL FEE SETTING*.—Section 744B(d)(1) of the
 6 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
 7 42(d)(1)) is amended—

8 (1) in the heading, by striking “2018 THROUGH
 9 2022” and inserting “2023 THROUGH 2027”;

10 (2) by striking “more” and inserting “later”;
 11 and

12 (3) by striking “2018 through 2022” and insert-
 13 ing “2023 through 2027”.

14 (e) *EFFECT OF FAILURE TO PAY FEES*.—The heading
 15 of paragraph (3) of section 744B(g) of the *Federal Food,*
 16 *Drug, and Cosmetic Act* (21 U.S.C. 379j–42(g)) is amended
 17 by striking “AND PRIOR APPROVAL SUPPLEMENT FEE”.

18 (f) *CREDITING AND AVAILABILITY OF FEES*.—Section
 19 744B(i)(3) of the *Federal Food, Drug, and Cosmetic Act*
 20 (21 U.S.C. 379j–42(i)(3)) is amended by striking “2018
 21 through 2022” and inserting “2023 through 2027”.

22 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

23 Section 744C of the *Federal Food, Drug, and Cosmetic*
 24 *Act* (21 U.S.C. 379j–43) is amended—

25 (1) in subsection (a)—

1 (A) by striking “2018” each place it ap-
 2 pears and inserting “2023”; and

3 (B) by striking “Generic Drug User Fee
 4 Amendments of 2017” each place it appears and
 5 inserting “Generic Drug User Fee Amendments
 6 of 2022”;

7 (2) in subsection (b), by striking “2018” and in-
 8 serting “2023”;

9 (3) in subsection (c)—

10 (A) by striking “2018” and inserting
 11 “2023”; and

12 (B) by striking “Generic Drug User Fee
 13 Amendments of 2017” each place it appears and
 14 inserting “Generic Drug User Fee Amendments
 15 of 2022”; and

16 (4) in subsection (f)—

17 (A) in paragraph (1), by striking “2022”
 18 and inserting “2027”; and

19 (B) in paragraph (5), by striking “January
 20 15, 2022” and inserting “January 15, 2027”.

21 **SEC. 304. SUNSET DATES.**

22 (a) *AUTHORIZATION.*—Sections 744A and 744B of the
 23 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
 24 41; 379j–42) shall cease to be effective October 1, 2027.

1 (b) *REPORTING REQUIREMENTS.*—Section 744C of the
 2 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
 3 43) shall cease to be effective January 31, 2028.

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
 5 1, 2022, subsections (a) and (b) of section 305 of the *FDA*
 6 *Reauthorization Act of 2017* (Public Law 115–52) are re-
 7 pealed.

8 **SEC. 305. EFFECTIVE DATE.**

9 *The amendments made by this title shall take effect*
 10 *on October 1, 2022, or the date of the enactment of this*
 11 *Act, whichever is later, except that fees under part 7 of sub-*
 12 *chapter C of chapter VII of the Federal Food, Drug, and*
 13 *Cosmetic Act* (21 U.S.C. 379j–41 *et seq.*) shall be assessed
 14 *for all abbreviated new drug applications received on or*
 15 *after October 1, 2022, regardless of the date of the enactment*
 16 *of this Act.*

17 **SEC. 306. SAVINGS CLAUSE.**

18 *Notwithstanding the amendments made by this title,*
 19 *part 7 of subchapter C of chapter VII of the Federal Food,*
 20 *Drug, and Cosmetic Act, as in effect on the day before the*
 21 *date of the enactment of this title, shall continue to be in*
 22 *effect with respect to abbreviated new drug applications (as*
 23 *defined in such part as of such day) that were received by*
 24 *the Food and Drug Administration within the meaning of*
 25 *section 505(j)(5)(A) of such Act* (21 U.S.C. 355(j)(5)(A)),

1 *prior approval supplements that were submitted, and drug*
 2 *master files for Type II active pharmaceutical ingredients*
 3 *that were first referenced on or after October 1, 2017, but*
 4 *before October 1, 2022, with respect to assessing and col-*
 5 *lecting any fee required by such part for a fiscal year prior*
 6 *to fiscal year 2023.*

7 ***TITLE IV—FEES RELATING TO***
 8 ***BIOSIMILAR BIOLOGICAL***
 9 ***PRODUCTS***

10 ***SEC. 401. SHORT TITLE; FINDING.***

11 (a) *SHORT TITLE.*—*This title may be cited as the*
 12 *“Biosimilar User Fee Amendments of 2022”.*

13 (b) *FINDING.*—*Congress finds that the fees authorized*
 14 *by the amendments made in this title will be dedicated to*
 15 *expediting the process for the review of biosimilar biological*
 16 *product applications, including postmarket safety activi-*
 17 *ties, as set forth in the goals identified for purposes of part*
 18 *8 of subchapter C of chapter VII of the Federal Food, Drug,*
 19 *and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the letters*
 20 *from the Secretary of Health and Human Services to the*
 21 *Chairman of the Committee on Health, Education, Labor,*
 22 *and Pensions of the Senate and the Chairman of the Com-*
 23 *mittee on Energy and Commerce of the House of Represent-*
 24 *atives, as set forth in the Congressional Record.*

1 **SEC. 402. DEFINITIONS.**

2 *Section 744G of the Federal Food, Drug, and Cosmetic*
 3 *Act (21 U.S.C. 379j–51) is amended—*

4 *(1) in paragraph (1)—*

5 *(A) by striking “Washington-Baltimore,*
 6 *DC–MD–VA–WV” and inserting “Washington–*
 7 *Arlington–Alexandria, DC–VA–MD–WV”;*

8 *(B) by striking “October of” and inserting*
 9 *“September of”; and*

10 *(C) by striking “October 2011” and insert-*
 11 *ing “September 2011”; and*

12 *(2) in paragraph (4)(B)(iii)—*

13 *(A) by striking subclause (II); and*

14 *(B) by redesignating subclauses (III) and*
 15 *(IV) as subclauses (II) and (III), respectively.*

16 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIO-**
 17 **LOGICAL PRODUCT FEES.**

18 *(a) TYPES OF FEES.—Section 744H(a) of the Federal*
 19 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is*
 20 *amended—*

21 *(1) in the matter preceding paragraph (1), by*
 22 *striking “2018” and inserting “2023”;*

23 *(2) in paragraph (1)—*

24 *(A) in subparagraph (A)—*

25 *(i) in clause (iv)(I), by striking “5*
 26 *days” and inserting “7 days”; and*

(ii) in clause (v)(II), by striking “5 days” and inserting “7 days”;

(B) in subparagraph (B)—

(i) in clause (i), by inserting “, except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee or successor shall pay the annual biosimilar biological product development fee” before the period;

(ii) in clause (iii)—

(I) in subclause (I), by striking “; or” and inserting a semicolon;

(II) in subclause (II), by striking the period and inserting “; or”; and

(III) by adding at the end the following:

“(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).”; and

1 *(iii) in clause (iv), by striking “accept-*
 2 *ed for filing on or after October 1 of such*
 3 *fiscal year” and inserting “subsequently ac-*
 4 *cepted for filing”;*

5 *(C) in subparagraph (D)—*

6 *(i) in clause (i)—*

7 *(I) in the matter preceding sub-*
 8 *clause (I), by striking “shall, if the*
 9 *person seeks to resume participation in*
 10 *such program, pay” and inserting “or*
 11 *who has been administratively removed*
 12 *from such program for a product*
 13 *under subparagraph (E)(v) shall, if the*
 14 *person seeks to resume participation in*
 15 *such program, pay all annual bio-*
 16 *similar biological product development*
 17 *fees previously assessed for such prod-*
 18 *uct and still owed and”;*

19 *(II) in subclause (I)—*

20 *(aa) by striking “5 days”*
 21 *and inserting “7 days”; and*

22 *(bb) by inserting “or the date*
 23 *of administrative removal, as ap-*
 24 *plicable” after “discontinued”;*
 25 *and*

1 (III) in subclause (II), by insert-
 2 ing “or the date of administrative re-
 3 moval, as applicable” after “discon-
 4 tinued”; and

5 (ii) in clause (ii), by inserting “, ex-
 6 cept that, in the case that such product (in-
 7 cluding, where applicable, ownership of the
 8 relevant investigational new drug applica-
 9 tion) is transferred to a licensee, assignee,
 10 or successor of such person, and written no-
 11 tice of such transfer is provided to the Sec-
 12 retary, such licensee, assignee or successor
 13 shall pay the annual biosimilar biological
 14 product development fee” before the period
 15 at the end; and

16 (D) in subparagraph (E), by adding at the
 17 end the following:

18 “(v) ADMINISTRATIVE REMOVAL FROM
 19 THE BIOSIMILAR BIOLOGICAL PRODUCT DE-
 20 VELOPMENT PROGRAM.—If a person has
 21 failed to pay an annual biosimilar biologi-
 22 cal product development fee for a product as
 23 required under subparagraph (B) for a pe-
 24 riod of 2 consecutive fiscal years, the Sec-
 25 retary may administratively remove such

1 *person from the biosimilar biological prod-*
 2 *uct development program for the product.*
 3 *At least 30 days prior to administratively*
 4 *removing a person from the biosimilar bio-*
 5 *logical product development program for a*
 6 *product under this clause, the Secretary*
 7 *shall provide written notice to such person*
 8 *of the intended administrative removal.”;*

9 (3) *in paragraph (2)(D), by inserting “prior to*
 10 *approval” after “withdrawn”;*

11 (4) *in paragraph (3)—*

12 (A) *in subparagraph (A)—*

13 (i) *in clause (i), by striking “; and”*
 14 *and inserting a semicolon;*

15 (ii) *by redesignating clause (ii) as*
 16 *clause (iii); and*

17 (iii) *by inserting the following after*
 18 *clause (i):*

19 “(ii) *may be dispensed only under pre-*
 20 *scription pursuant to section 503(b); and”;*
 21 *and*

22 (B) *by adding at the end the following:*

23 “(E) *MOVEMENT TO DISCONTINUED LIST.—*

24 “(i) *WRITTEN REQUEST TO PLACE ON*
 25 *DISCONTINUED LIST.—*

1 “(I) *IN GENERAL.*—If a written
2 request to place a product on the list of
3 discontinued biosimilar biological
4 products referred to in subparagraph
5 (A)(iii) is submitted to the Secretary
6 on behalf of an applicant, and the re-
7 quest identifies the date the product is,
8 or will be, withdrawn from sale, then
9 for purposes of assessing the biosimilar
10 biological product program fee, the
11 Secretary shall consider such product
12 to have been included on such list on
13 the later of—

14 “(aa) the date such request
15 was received; or

16 “(bb) if the product will be
17 withdrawn from sale on a future
18 date, such future date when the
19 product is withdrawn from sale.

20 “(II) *WITHDRAWN FROM SALE*
21 *DEFINED.*—For purposes of this clause,
22 a product shall be considered with-
23 drawn from sale once the applicant has
24 ceased its own distribution of the prod-
25 uct, whether or not the applicant has

1 *ordered recall of all previously distrib-*
2 *uted lots of the product, except that a*
3 *routine, temporary interruption in*
4 *supply shall not render a product*
5 *withdrawn from sale.*

6 “(ii) *PRODUCTS REMOVED FROM DIS-*
7 *CONTINUED LIST.—If a biosimilar biologi-*
8 *cal product that is identified in a bio-*
9 *similar biological product application ap-*
10 *proved as of October 1 of a fiscal year ap-*
11 *pears, as of October 1 of such fiscal year, on*
12 *the list of discontinued biosimilar biological*
13 *products referred to in subparagraph*
14 *(A)(iii), and on any subsequent day during*
15 *such fiscal year the biosimilar biological*
16 *product does not appear on such list, except*
17 *as provided in subparagraph (D), each per-*
18 *son who is named as the applicant in the*
19 *biosimilar biological product application*
20 *shall pay the annual biosimilar biological*
21 *product program fee established for a fiscal*
22 *year under subsection (c)(5) for such bio-*
23 *similar biological product. Notwithstanding*
24 *subparagraph (B), such fee shall be due on*
25 *the last business day of such fiscal year and*

1 *shall be paid only once for each product for*
 2 *each fiscal year.”; and*

3 *(5) by striking paragraph (4).*

4 ***(b) FEE REVENUE AMOUNTS.***—*Section 744H(b) of the*
 5 *Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 379j–*
 6 *52(b)) is amended—*

7 *(1) by striking paragraph (1);*

8 *(2) by redesignating paragraphs (2) through (4)*
 9 *as paragraphs (1) through (3), respectively;*

10 *(3) in paragraph (1), as so redesignated—*

11 *(A) in the paragraph heading, by striking*
 12 *“SUBSEQUENT FISCAL YEARS” and inserting “IN*
 13 *GENERAL”;*

14 *(B) in the matter preceding subparagraph*
 15 *(A), by striking “2019 through 2022” and insert-*
 16 *ing “2023 through 2027”;*

17 *(C) in subparagraph (A), by striking*
 18 *“paragraph (4)” and inserting “paragraph (3)”;*

19 *(D) by redesignating subparagraphs (C)*
 20 *and (D) as subparagraphs (D) and (E), respec-*
 21 *tively;*

22 *(E) by inserting after subparagraph (B) the*
 23 *following:*

1 “(C) the dollar amount equal to the stra-
 2 tegic hiring and retention adjustment (as deter-
 3 mined under subsection (c)(2));”;

4 (F) in subparagraph (D), as so redesign-
 5 ated, by striking “subsection (c)(2)); and” and
 6 inserting “subsection (c)(3));”;

7 (G) in subparagraph (E), as so redesign-
 8 ated, by striking “subsection (c)(3)).” and in-
 9 serting “subsection (c)(4)); and”; and

10 (H) by adding at the end the following:

11 “(F) for fiscal years 2023 and 2024, addi-
 12 tional dollar amounts equal to—

13 “(i) \$4,428, 886 for fiscal year 2023;

14 and

15 “(ii) \$320,569 for fiscal year 2024.”;

16 (4) in paragraph (2), as so redesignated—

17 (A) in the paragraph heading, by striking
 18 “; LIMITATIONS ON FEE AMOUNTS”;

19 (B) by striking subparagraph (B); and

20 (C) by redesignating subparagraphs (C)
 21 and (D) as subparagraphs (B) and (C), respec-
 22 tively; and

23 (5) by amending paragraph (3), as so redesign-
 24 ated, to read as follows:

1 “(3) *ANNUAL BASE REVENUE*.—For purposes of
2 *paragraph (1), the dollar amount of the annual base*
3 *revenue for a fiscal year shall be—*

4 “(A) *for fiscal year 2023, \$43,376,922; and*

5 “(B) *for fiscal years 2024 through 2027, the*
6 *dollar amount of the total revenue amount estab-*
7 *lished under paragraph (1) for the previous fis-*
8 *cal year, excluding any adjustments to such rev-*
9 *enue amount under subsection (c)(4).”.*

10 (c) *ADJUSTMENTS; ANNUAL FEE SETTING*.—Section
11 *744H(c) of the Federal Food, Drug, and Cosmetic Act ((21*
12 *U.S.C. 379j–52(c)) is amended—*

13 (1) *in paragraph (1)—*

14 (A) *in subparagraph (A)—*

15 (i) *in the matter preceding clause (i),*
16 *by striking “subsection (b)(2)(B)” and in-*
17 *serting “subsection (b)(1)(B)”;* and

18 (ii) *in clause (i), by striking “sub-*
19 *section (b)” and inserting “subsection*
20 *(b)(1)(A)”;* and

21 (B) *in subparagraph (B)(ii), by striking*
22 *“Washington-Baltimore, DC–MD–VA–WV” and*
23 *inserting “Washington–Arlington–Alexandria,*
24 *DC–VA–MD–WV”;*

25 (2) *by striking paragraph (4);*

1 (3) by redesignating paragraphs (2) and (3) as
2 paragraphs (3) and (4), respectively;

3 (4) by inserting after paragraph (1) the fol-
4 lowing:

5 “(2) *STRATEGIC HIRING AND RETENTION AD-*
6 *JUSTMENT.—For each fiscal year beginning in fiscal*
7 *year 2023, after the annual base revenue under sub-*
8 *section (b)(1)(A) is adjusted for inflation in accord-*
9 *ance with paragraph (1), the Secretary shall further*
10 *increase the fee revenue and fees by \$150,000.”;*

11 (5) in paragraph (3), as so redesignated—

12 (A) in subparagraph (A)—

13 (i) by striking “Beginning with the fis-
14 cal year described in subparagraph
15 (B)(ii)(II)” and inserting “For each fiscal
16 year”; and

17 (ii) by striking “adjustment under
18 paragraph (1), further increase” and insert-
19 ing “adjustments under paragraphs (1) and
20 (2), further adjust”; and

21 (B) by amending subparagraph (B) to read
22 as follows:

23 “(B) *METHODOLOGY.—For purposes of this*
24 *paragraph, the Secretary shall employ the capac-*
25 *ity planning methodology utilized by the Sec-*

1 *retary in setting fees for fiscal year 2021, as de-*
 2 *scribed in the notice titled ‘Biosimilar User Fee*
 3 *Rates for Fiscal Year 2021’ (85 Fed. Reg. 47220;*
 4 *August 4, 2020). The workload categories used in*
 5 *forecasting shall include only the activities de-*
 6 *scribed in such notice and, as feasible, additional*
 7 *activities that are also directly related to the di-*
 8 *rect review of biosimilar biological product ap-*
 9 *plications and supplements, including additional*
 10 *formal meeting types and the direct review of*
 11 *postmarketing commitments and requirements,*
 12 *the direct review of risk evaluation and mitiga-*
 13 *tion strategies, and the direct review of annual*
 14 *reports for approved biosimilar biological prod-*
 15 *ucts. Subject to the exceptions in the preceding*
 16 *sentence, the Secretary shall not include as work-*
 17 *load categories in forecasting any non-core re-*
 18 *view activities, including any activities that the*
 19 *Secretary referenced for potential future use in*
 20 *such notice but did not utilize in setting fees for*
 21 *fiscal year 2021.’; and*

22 (C) in subparagraph (C)—

23 (i) by striking “subsections (b)(2)(A)”
 24 and inserting “subsections (b)(1)(A)”;

1 (ii) by striking “and (b)(2)(B)” and
 2 inserting “, (b)(1)(B)”;

3 (iii) by inserting “, and (b)(1)(C) (the
 4 dollar amount of the strategic hiring and
 5 retention adjustment)” before the period at
 6 the end;

7 (6) by amending paragraph (4), as so redesign-
 8 ated, to read as follows:

9 “(4) *OPERATING RESERVE ADJUSTMENT.*—

10 “(A) *INCREASE.*—For fiscal year 2023 and
 11 subsequent fiscal years, the Secretary shall, in
 12 addition to adjustments under paragraphs (1),
 13 (2), and (3), further increase the fee revenue and
 14 fees if such an adjustment is necessary to provide
 15 for at least 10 weeks of operating reserves of car-
 16 ryover user fees for the process for the review of
 17 biosimilar biological product applications.

18 “(B) *DECREASE.*—

19 “(i) *FISCAL YEAR 2023.*—For fiscal
 20 year 2023, if the Secretary has carryover
 21 balances for the process for the review of
 22 biosimilar biological product applications
 23 in excess of 33 weeks of such operating re-
 24 serves, the Secretary shall decrease such fee

1 *revenue and fees to provide for not more*
2 *than 33 weeks of such operating reserves.*

3 “(ii) *FISCAL YEAR 2024.—For fiscal*
4 *year 2024, if the Secretary has carryover*
5 *balances for the process for the review of*
6 *biosimilar biological product applications*
7 *in excess of 27 weeks of such operating re-*
8 *serves, the Secretary shall decrease such fee*
9 *revenue and fees to provide for not more*
10 *than 27 weeks of such operating reserves.*

11 “(iii) *FISCAL YEAR 2025 AND SUBSE-*
12 *QUENT FISCAL YEARS.—For fiscal year*
13 *2025 and subsequent fiscal years, if the Sec-*
14 *retary has carryover balances for the process*
15 *for the review of biosimilar biological prod-*
16 *uct applications in excess of 21 weeks of*
17 *such operating reserves, the Secretary shall*
18 *decrease such fee revenue and fees to provide*
19 *for not more than 21 weeks of such oper-*
20 *ating reserves.*

21 “(C) *FEDERAL REGISTER NOTICE.—If an*
22 *adjustment under subparagraph (A) or (B) is*
23 *made, the rationale for the amount of the in-*
24 *crease or decrease (as applicable) in fee revenue*
25 *and fees shall be contained in the annual Federal*

1 *Register notice under paragraph (5)(B) estab-*
 2 *lishing fee revenue and fees for the fiscal year in-*
 3 *volved.”; and*

4 *(7) in paragraph (5), in the matter preceding*
 5 *subparagraph (A), by striking “2018” and inserting*
 6 *“2023”.*

7 *(d) CREDITING AND AVAILABILITY OF FEES.—Section*
 8 *744H(f)(3) of the Federal Food, Drug, and Cosmetic Act*
 9 *((21 U.S.C. 379j–52(f)(3)) is amended by striking “2018*
 10 *through 2022” and inserting “2023 through 2027”.*

11 *(e) WRITTEN REQUESTS FOR WAIVERS AND RE-*
 12 *FUNDS.—Subsection (h) of section 744H of the Federal*
 13 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is*
 14 *amended to read as follows:*

15 *“(h) WRITTEN REQUESTS FOR WAIVERS AND RE-*
 16 *URNS; DISPUTES CONCERNING FEES.—To qualify for con-*
 17 *sideration for a waiver under subsection (d), or the return*
 18 *of any fee paid under this section, including if the fee is*
 19 *claimed to have been paid in error, a person shall submit*
 20 *to the Secretary a written request justifying such waiver*
 21 *or return and, except as otherwise specified in this section,*
 22 *such written request shall be submitted to the Secretary not*
 23 *later than 180 days after such fee is due. A request sub-*
 24 *mitted under this paragraph shall include any legal au-*
 25 *thorities under which the request is made.”.*

1 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

2 *Section 744I of the Federal Food, Drug, and Cosmetic*
 3 *Act (21 U.S.C. 379j–53) is amended—*

4 *(1) by striking “2018” each place it appears and*
 5 *inserting “2023”;*

6 *(2) by striking “Biosimilar User Fee Amend-*
 7 *ments of 2017” each place it appears and inserting*
 8 *“Biosimilar User Fee Amendments of 2022”;*

9 *(3) in subsection (a)(4), by striking “2020” and*
 10 *inserting “2023”; and*

11 *(4) in subsection (f), by striking “2022” each*
 12 *place it appears and inserting “2027”.*

13 **SEC. 405. SUNSET DATES.**

14 *(a) AUTHORIZATION.—Sections 744G and 744H of the*
 15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 16 *51, 379j–52) shall cease to be effective October 1, 2027.*

17 *(b) REPORTING REQUIREMENTS.—Section 744I of the*
 18 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 19 *53) shall cease to be effective January 31, 2028.*

20 *(c) PREVIOUS SUNSET PROVISION.—Effective October*
 21 *1, 2022, subsections (a) and (b) of section 405 of the FDA*
 22 *Reauthorization Act of 2017 (Public Law 115–52) are re-*
 23 *pealed.*

24 **SEC. 406. EFFECTIVE DATE.**

25 *The amendments made by this title shall take effect*
 26 *on October 1, 2022, or the date of the enactment of this*

1 *Act, whichever is later, except that fees under part 8 of sub-*
 2 *chapter C of chapter VII of the Federal Food, Drug, and*
 3 *Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed*
 4 *for all biosimilar biological product applications received*
 5 *on or after October 1, 2022, regardless of the date of the*
 6 *enactment of this Act.*

7 **SEC. 407. SAVINGS CLAUSE.**

8 *Notwithstanding the amendments made by this title,*
 9 *part 8 of subchapter C of chapter VII of the Federal Food,*
 10 *Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as in*
 11 *effect on the day before the date of the enactment of this*
 12 *title, shall continue to be in effect with respect to biosimilar*
 13 *biological product applications and supplements (as defined*
 14 *in such part as of such day) that were accepted by the Food*
 15 *and Drug Administration for filing on or after October 1,*
 16 *2017, but before October 1, 2022, with respect to assessing*
 17 *and collecting any fee required by such part for a fiscal*
 18 *year prior to fiscal year 2023.*

19 **TITLE V—IMPROVING REGULA-**
 20 **TION OF DRUGS AND BIO-**
 21 **LOGICAL PRODUCTS**

22 **SEC. 501. ALTERNATIVES TO ANIMAL TESTING.**

23 *(a) IN GENERAL.—Section 505 of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 355) is amended—*

25 *(1) in subsection (i)—*

(A) in paragraph (1)(A), by striking “pre-clinical tests (including tests on animals)” and inserting “nonclinical tests”; and

4 (B) in paragraph (2)(B), by striking “ani-
5 mal” and inserting “nonclinical tests”; and

(2) after subsection (y), by inserting the following:

8 “(z) *NONCLINICAL TEST DEFINED.*—For purposes of
9 this section, the term ‘nonclinical test’ means a test con-
10 ducted *in vitro*, *in silico*, or *in chemico*, or a non-human
11 *in vivo* test that occurs before or during the clinical trial
12 phase of the investigation of the safety and effectiveness of
13 a drug, and may include animal tests, or non-animal or
14 human biology-based test methods, such as cell-based assays,
15 microphysiological systems, or bioprinted or computer mod-
16 els.”.

(b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I)) is amended to read as follows:

21 “(bb) an assessment of tox-
22 icity (which may rely on, or con-
23 sist of, a study or studies de-
24 scribed in item (aa) or (cc));
25 and”.

1 **SEC. 502. SAFER DISPOSAL OF OPIOIDS.**

2 Section 505–1(e)(4)(B) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355–1(e)(4)(B)) is amended by
4 striking “for purposes of rendering drugs nonretrievable (as
5 defined in section 1300.05 of title 21, Code of Federal Regu-
6 lations (or any successor regulation))”.

7 **SEC. 503. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS**
8 **FOR FIRST INTERCHANGEABLE BIOSIMILAR**
9 **BIOLOGICAL PRODUCTS.**

10 Section 351(k)(6) of the Public Health Service Act (42
11 U.S.C. 262(k)(6)) is amended—

12 (1) in the matter preceding subparagraph (A)—

13 (A) by striking “Upon review of” and in-
14 serting “The Secretary shall not make approval
15 as an interchangeable biological product effective
16 with respect to”;

17 (B) by striking “relying on” and inserting
18 “that relies on”; and

19 (C) by striking “the Secretary shall not
20 make a determination under paragraph (4) that
21 the second or subsequent biological product is
22 interchangeable for any condition of use”; and

23 (2) in the flush text that follows subparagraph
24 (C), by striking the period and inserting “, and the
25 term ‘first interchangeable biosimilar biological prod-
26 uct’ means any interchangeable biosimilar biological

1 *product that is approved on the first day on which*
 2 *such a product is approved as interchangeable with*
 3 *the reference product.”.*

4 **SEC. 504. IMPROVEMENTS TO THE PURPLE BOOK.**

5 (a) *IN GENERAL.*—Section 506I of the Federal Food,
 6 *Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—*

7 (1) *in subsection (a)—*

8 (A) *by striking “The holder of an applica-*
 9 *tion approved under subsection (c) or (j) of sec-*
 10 *tion 505” and inserting “The holder of an appli-*
 11 *cation approved under subsection (c) or (j) of*
 12 *section 505 of this Act or subsection (a) or (k)*
 13 *of section 351 of the Public Health Service Act”;*

14 (B) *in paragraph (2), by inserting “(in the*
 15 *case of a biological product, the proper name)”*
 16 *after “established name”; and*

17 (C) *in paragraph (3), by striking “or abbrev-*
 18 *viated application number” and inserting “, ab-*
 19 *breviated application number, or biologics license*
 20 *application number”; and*

21 (2) *in subsection (b)—*

22 (A) *in the matter preceding paragraph (1),*
 23 *by striking “The holder of an application ap-*
 24 *proved under subsection (c) or (j)” and inserting*
 25 *“The holder of an application approved under*

1 *subsection (c) or (j) of section 505 of this Act or*
 2 *subsection (a) or (k) of section 351 of the Public*
 3 *Health Service Act”;*

4 *(B) in paragraph (1), by inserting “(in the*
 5 *case of a biological product, the proper name)”*
 6 *after “established name”; and*

7 *(C) in paragraph (2), by striking “or abbrev-*
 8 *viated application number” and inserting “, ab-*
 9 *breviated application number, or biologics license*
 10 *application number”.*

11 *(b) ADDITIONAL ONE-TIME REPORT.—Subsection (c)*
 12 *of section 506I of the Federal Food, Drug, and Cosmetic*
 13 *Act (21 U.S.C. 356i) is amended to read as follows:*

14 *“(c) ADDITIONAL ONE-TIME REPORT.—Within 180*
 15 *days of the date of enactment of the Food and Drug Admin-*
 16 *istration Safety and Landmark Advancements Act of 2022,*
 17 *all holders of applications approved under subsection (a)*
 18 *or (k) of section 351 of the Public Health Service Act shall*
 19 *review the information in the list published under section*
 20 *351(k)(9)(A) and shall submit a written notice to the Sec-*
 21 *retary—*

22 *“(1) stating that all of the application holder’s*
 23 *biological products in the list published under section*
 24 *351(k)(9)(A) that are not listed as discontinued are*
 25 *available for sale; or*

1 “(2) including the information required pursu-
 2 ant to subsection (a) or (b), as applicable, for each of
 3 the application holder’s biological products that are
 4 in the list published under section 351(k)(9)(A) and
 5 not listed as discontinued, but have been discontinued
 6 from sale or never have been available for sale.”.

7 (c) *PURPLE BOOK*.—Section 506I of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

9 (1) in subsection (d)—

10 (A) by striking “or (c), the Secretary” and
 11 inserting “or (c)—

12 “(1) the Secretary”;

13 (B) by striking the period at the end, and
 14 inserting “; and”; and

15 (C) by adding at the end the following:

16 “(2) the Secretary may identify the application
 17 holder’s biological products as discontinued in the list
 18 published under section 351(k)(9)(A) of the Public
 19 Health Service Act, except that the Secretary shall re-
 20 move from the list in accordance with section
 21 351(k)(9)(B) of such Act any biological product for
 22 which a license has been revoked or suspended for rea-
 23 sons of safety, purity, or potency.”; and

24 (2) in subsection (e)—

1 (A) by inserting after the first sentence the
 2 following: “The Secretary shall update the list
 3 published under section 351(k)(9)(A) of the Pub-
 4 lic Health Service Act based on information pro-
 5 vided under subsections (a), (b), and (c) by iden-
 6 tifying as discontinued biological products that
 7 are not available for sale, except that any bio-
 8 logical product for which the license has been re-
 9 voked or suspended for reasons of safety, purity,
 10 or potency shall be removed from the list in ac-
 11 cordance with section 351(k)(9)(B) of the Public
 12 Health Service Act.”; and

13 (B) in the last sentence—

14 (i) by striking “updates to the list”
 15 and inserting “updates to the lists published
 16 under section 505(j)(7)(A) of this Act and
 17 section 351(k)(9)(A) of the Public Health
 18 Service Act”; and

19 (ii) by striking “update the list” and
 20 inserting “update such lists”.

21 **SEC. 505. THERAPEUTIC EQUIVALENCE EVALUATIONS.**

22 Section 505(j)(7)(A) of the Federal Food, Drug, and
 23 Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by add-
 24 ing at the end the following:

1 “(v)(I) *With respect to an application submitted pur-*
2 *suant to subsection (b)(2) for a drug that is subject to sec-*
3 *tion 503(b) for which the sole difference from a listed drug*
4 *relied upon in the application is a difference in inactive*
5 *ingredients not permitted under clause (iii) or (iv) of sec-*
6 *tion 314.94(a)(9) of title 21, Code of Federal Regulations*
7 *(or any successor regulations), the Secretary shall make an*
8 *evaluation with respect to whether such drug is a thera-*
9 *peutic equivalent (as defined in section 314.3 of title 21,*
10 *Code of Federal Regulations (or any successor regulations))*
11 *to another approved drug product in the prescription drug*
12 *product section of the list under this paragraph as follows:*

13 “(aa) *With respect to such an application sub-*
14 *mitted after the date of enactment of the Food and*
15 *Drug Administration Safety and Landmark Advance-*
16 *ments Act of 2022, the evaluation shall be made with*
17 *respect to a listed drug relied upon in the application*
18 *pursuant to subsection (b)(2) that is a pharma-*
19 *ceutical equivalent (as defined in section 314.3 of title*
20 *21, Code of Federal Regulations (or any successor reg-*
21 *ulations)) to the drug in the application pursuant to*
22 *subsection (b)(2) at the time of approval of such ap-*
23 *plication or not later than 180 days after the date of*
24 *such approval, provided that the request for such an*
25 *evaluation is made in the original application (or in*

1 *a resubmission to a complete response letter), and all*
2 *necessary data and information are submitted in the*
3 *original application (or in a resubmission in response*
4 *to a complete response letter) for the therapeutic*
5 *equivalence evaluation, including information to dem-*
6 *onstrate bioequivalence, in a form and manner pre-*
7 *scribed by the Secretary.*

8 *“(bb) With respect to such an application ap-*
9 *proved prior to or on the date of enactment of the*
10 *Food and Drug Administration Safety and Land-*
11 *mark Advancements Act of 2022, the evaluation shall*
12 *be made not later than 180 days after receipt of a re-*
13 *quest for a therapeutic equivalence evaluation sub-*
14 *mitted as part of a supplement to such application;*
15 *or with respect to an application that was submitted*
16 *prior to the date of enactment of the Food and Drug*
17 *Administration Safety and Landmark Advancements*
18 *Act of 2022 but not approved as of the date of enact-*
19 *ment of such Act, the evaluation shall be made not*
20 *later than 180 days after the date of approval of such*
21 *application if a request for such evaluation is sub-*
22 *mitted as an amendment to the application, provided*
23 *that—*

24 *“(AA) such request for a therapeutic equiva-*
25 *lence evaluation is being sought with respect to*

1 *a listed drug relied upon in the application, and*
 2 *the relied upon listed drug is in the prescription*
 3 *drug product section of the list under this para-*
 4 *graph and is a pharmaceutical equivalent (as*
 5 *defined in section 314.3 of title 21, Code of Fed-*
 6 *eral Regulations (or any successor regulations))*
 7 *to the drug for which a therapeutic equivalence*
 8 *evaluation is sought; and*

9 *“(BB) the amendment or supplement, as*
 10 *applicable, containing such request, or the rel-*
 11 *evant application, includes all necessary data*
 12 *and information for the therapeutic equivalence*
 13 *evaluation, including information to dem-*
 14 *onstrate bioequivalence, in a form and manner*
 15 *prescribed by the Secretary.*

16 *“(II) When the Secretary makes an evaluation under*
 17 *subclause (I), the Secretary shall, in revisions made to the*
 18 *list pursuant to clause (ii), include such information for*
 19 *such drug.”.*

20 **SEC. 506. MODERNIZING ACCELERATED APPROVAL.**

21 *(a) IN GENERAL.—Section 506(c) of the Federal Food,*
 22 *Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended—*
 23 *(1) in paragraph (2)—*

1 (A) by redesignating subparagraphs (A)
2 and (B) as clauses (i) and (ii), respectively, and
3 adjusting the margins accordingly;

4 (B) by striking “Approval of a product”
5 and inserting the following:

6 “(A) *IN GENERAL.*—Approval of a prod-
7 uct”;

8 (C) in clause (i) of such subparagraph (A),
9 as so redesignated, by striking “appropriate
10 postapproval studies” and inserting “an appro-
11 priate postapproval study or studies (which may
12 be augmented or supported by real world evi-
13 dence)”; and

14 (D) by adding at the end the following:

15 “(B) *STUDIES NOT REQUIRED.*—If the Sec-
16 retary does not require that the sponsor of a
17 product approved under accelerated approval
18 conduct a postapproval study under this para-
19 graph, the Secretary shall publish on the website
20 of the Food and Drug Administration the ration-
21 ale for why such study is not appropriate or nec-
22 essary.

23 “(C) *POSTAPPROVAL STUDY CONDITIONS.*—
24 Not later than the date of approval of a product
25 under accelerated approval, the Secretary shall

specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

“(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require such study or studies to be underway prior to approval of the applicable product.”; and
(2) in paragraph (3)—

(A) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively and adjusting the margins accordingly;

(B) by striking “The Secretary may” and inserting the following:

“(A) IN GENERAL.—The Secretary may”;

(C) in clause (i) of such subparagraph (A), as so redesignated, by striking “drug with due diligence” and inserting “product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C)”;

(D) in clause (iii) of such subparagraph (A), as so redesignated, by inserting “shown to be” after “product is not”; and

1 (E) by adding at the end the following:

2 “(B) EXPEDITED PROCEDURES DE-
3 SCRIBED.—*Expedited procedures described in*
4 *this subparagraph shall consist of, prior to the*
5 *withdrawal of accelerated approval—*

6 “(i) providing the sponsor with—

7 “(I) due notice;

8 “(II) an explanation for the pro-
9 posed withdrawal;

10 “(III) an opportunity for a meet-
11 ing with the Commissioner or the Com-
12 missioner’s designee; and

13 “(IV) an opportunity for written
14 appeal to—

15 “(aa) the Commissioner; or

16 “(bb) a designee of the Com-
17 missioner who has not partici-
18 pated in the proposed withdrawal
19 of approval (other than a meeting
20 pursuant to subclause (III)) and
21 is not subordinate of an indi-
22 vidual (other than the Commis-
23 sioner) who participated in such
24 proposed withdrawal;

1 “(ii) providing an opportunity for
2 public comment on the proposal to with-
3 draw approval;

4 “(iii) the publication of a summary of
5 the public comments received, and the Sec-
6 retary’s response to such comments, on the
7 website of the Food and Drug Administra-
8 tion; and

9 “(iv) convening and consulting an ad-
10 visory committee on issues related to the
11 proposed withdrawal, if requested by the
12 sponsor and if no such advisory committee
13 has previously advised the Secretary on
14 such issues with respect to the withdrawal
15 of the product prior to the sponsor’s re-
16 quest.”.

17 (b) *REPORTS OF POSTMARKETING STUDIES.*—Section
18 506B(a) of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 356b(a)) is amended—

20 (1) by redesignating paragraph (2) as para-
21 graph (3); and

22 (2) by inserting after paragraph (1) the fol-
23 lowing:

24 “(2) *ACCELERATED APPROVAL.*—Notwith-
25 standing paragraph (1), a sponsor of a drug ap-

1 proved pursuant to accelerated approval shall submit
 2 to the Secretary a report of the progress of any study
 3 required under section 506(c), including progress to-
 4 ward enrollment targets, milestones, and other infor-
 5 mation as required by the Secretary, not later than
 6 180 days after the approval of such drug and not less
 7 frequently than every 180 days thereafter, until the
 8 study is completed or terminated. The Secretary shall
 9 promptly publish on the website of the Food and
 10 Drug Administration, in an easily searchable format,
 11 the information reported under this paragraph.”.

12 (c) *ENFORCEMENT.*—Section 301 of the Federal Food,
 13 Drug, and Cosmetic Act (21 U.S.C. 331) is amended by
 14 adding at the end the following:

15 “(fff) The failure of a sponsor of a product approved
 16 under accelerated approval pursuant to section 506(c)—

17 “(1) to conduct with due diligence any post-
 18 approval study required under section 506(c) with re-
 19 spect to such product; or

20 “(2) to submit timely reports with respect to
 21 such product in accordance with section 506B(a)(2).”.

22 (d) *GUIDANCE.*—

23 (1) *IN GENERAL.*—The Secretary of Health and
 24 Human Services (referred to in this section as the
 25 “Secretary”) shall issue guidance describing—

1 (A) how sponsor questions related to the
2 identification of novel surrogate or intermediate
3 clinical endpoints may be addressed in early-
4 stage development meetings with the Food and
5 Drug Administration;

6 (B) the use of novel clinical trial designs
7 that may be used to conduct appropriate post-
8 approval studies as may be required under sec-
9 tion 506(c)(2)(A) of the Federal Food, Drug, and
10 Cosmetic Act, as amended by subsection (a);

11 (C) the expedited procedures described in
12 section 506(c)(3)(B) of the Federal Food, Drug,
13 and Cosmetic Act; and

14 (D) considerations related to the use of sur-
15 rogate or intermediate clinical endpoints that
16 may support the accelerated approval of an ap-
17 plication under 506(c)(1)(A), including consider-
18 ations in evaluating the evidence related to any
19 such endpoints.

20 (2) *FINAL GUIDANCE.*—The Secretary shall
21 issue—

22 (A) draft guidance under paragraph (1) not
23 later than 18 months after the date of enactment
24 of this Act; and

1 (B) *final guidance not later than 1 year*
2 *after the close of the public comment period on*
3 *such draft guidance.*

4 (e) *ACCELERATED APPROVAL COUNCIL.*—

5 (1) *GENERAL.*—*Not later than 1 year after the*
6 *date of enactment of this Act, the Secretary shall es-*
7 *tablish an intra-agency coordinating council within*
8 *the Food and Drug Administration to ensure the con-*
9 *sistent and appropriate use of accelerated approval*
10 *across the Food and Drug Administration, pursuant*
11 *to section 506(c) of the Federal Food, Drug, and Cos-*
12 *metic Act (21 U.S.C. 356(c)).*

13 (2) *MEMBERSHIP.*—*The members of the Council*
14 *shall consist of the following senior officials, or a des-*
15 *ignee of such official, from the Food and Drug Ad-*
16 *ministration and relevant Centers:*

17 (A) *The Director of the Center for Drug*
18 *Evaluation and Research.*

19 (B) *The Director of the Center for Biologics*
20 *Evaluation and Research.*

21 (C) *The Director of the Oncology Center of*
22 *Excellence.*

23 (D) *The Director of the Office of New*
24 *Drugs.*

1 (E) *The Director of the Office of Orphan*
 2 *Products Development.*

3 (F) *The Director of the Office of Tissues*
 4 *and Advanced Therapies.*

5 (G) *The Director of the Office of Medical*
 6 *Policy.*

7 (H) *At least 3 directors of review divisions*
 8 *or offices overseeing products approved under ac-*
 9 *celerated approval, including at least one direc-*
 10 *tor within the Office of Neuroscience.*

11 (3) *DUTIES OF THE COUNCIL.—*

12 (A) *MEETINGS.—The Council shall convene*
 13 *not fewer than 3 times per calendar year to dis-*
 14 *cuss issues related to accelerated approval, in-*
 15 *cluding any relevant cross-disciplinary ap-*
 16 *proaches related to product review with respect*
 17 *to accelerated approval.*

18 (B) *POLICY DEVELOPMENT.—The Council*
 19 *shall directly engage with product review teams*
 20 *to support the consistent and appropriate use of*
 21 *accelerated approval across the Food and Drug*
 22 *Administration. Such activities may include—*

23 (i) *developing guidance for Food and*
 24 *Drug Administration staff and best prac-*
 25 *tices for, and across, product review teams,*

1 *including with respect to communication*
2 *between sponsors and the Food and Drug*
3 *Administration and the review of products*
4 *under accelerated approval;*

5 *(ii) providing training for product re-*
6 *view teams; and*

7 *(iii) advising review divisions on prod-*
8 *uct-specific development, review, and with-*
9 *drawal of products under accelerated ap-*
10 *proval.*

11 (4) *PUBLICATION OF A REPORT.*—*Not later than*
12 *1 year after the date of enactment of this Act, and an-*
13 *nually thereafter, the council shall publish on the pub-*
14 *lic website of the Food and Drug Administration a*
15 *report on the activities of the council.*

16 (5) *SUMMARY APPROVAL INFORMATION.*—*With*
17 *respect to each new drug application for a new molec-*
18 *ular entity approved under section 505(c) of the Fed-*
19 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(c))*
20 *or biological product licensed under section 351(a) of*
21 *the Public Health Service Act (42 U.S.C. 262(a)) pur-*
22 *suant to accelerated approval under section 506(c) of*
23 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
24 *356(c)), the Secretary shall provide for the drug or*
25 *biologic action package a summary of the basis for*

1 *approval, including, as relates to such new molecular*
2 *entity, whether an advisory committee meeting was*
3 *held and a rationale for a determination by the Sec-*
4 *retary that a surrogate endpoint is reasonably likely*
5 *to predict clinical benefit.*

6 *(f) RULE OF CONSTRUCTION.—Nothing in this section*
7 *(including the amendments made by this section) shall be*
8 *construed to affect products approved pursuant to section*
9 *506(c) of the Federal Food, Drug, and Cosmetic Act (21*
10 *U.S.C. 356(c)) prior to the date of enactment of this Act.*

11 **SEC. 507. RARE DISEASE PILOT PROGRAM.**

12 *(a) IN GENERAL.—The Secretary of Health and*
13 *Human Services (referred to in this section as the “Sec-*
14 *retary”)* shall establish a pilot program under which the
15 *Secretary establishes procedures to provide increased inter-*
16 *action with sponsors of rare disease drug development pro-*
17 *grams for purposes of advancing the development of efficacy*
18 *endpoints, including surrogate and intermediate endpoints,*
19 *for drugs intended to treat rare diseases, including*
20 *through—*

21 *(1) determining eligibility of participants for*
22 *such program; and*

23 *(2) developing and implementing a process for*
24 *applying to, and participating in, such a program.*

1 (b) *PUBLIC WORKSHOPS.*—*The Secretary shall con-*
2 *duct up to 3 public workshops, which shall be completed*
3 *not later than September 30, 2026, to discuss topics relevant*
4 *to the development of endpoints for rare diseases, which*
5 *may include discussions about—*

6 (1) *novel endpoints developed through the pilot*
7 *program established under this section; and*

8 (2) *as appropriate, the use of real world evidence*
9 *and real world data to support the validation of effi-*
10 *cacy endpoints, including surrogate and intermediate*
11 *endpoints, for rare diseases.*

12 (c) *REPORT.*—*Not later than September 30, 2026, the*
13 *Secretary shall submit to the Committee on Health, Edu-*
14 *cation, Labor, and Pensions of the Senate and the Com-*
15 *mittee on Energy and Commerce of the House of Represent-*
16 *atives a report describing the outcomes of the pilot program*
17 *established under this section.*

18 (d) *GUIDANCE.*—*Not later than September 30, 2027,*
19 *the Secretary shall issue guidance describing best practices*
20 *and strategies for development of efficacy endpoints, includ-*
21 *ing surrogate and intermediate endpoints, for rare diseases.*

22 (e) *SUNSET.*—*The Secretary may not accept any new*
23 *application or request to participate in the program estab-*
24 *lished by this section on or after October 1, 2027.*

1 **SEC. 508. SUPPORTING REVIEW AND DEVELOPMENT OF**
2 **DRUGS TO TREAT RARE DISEASES.**

3 (a) *GAO REPORT.*—

4 (1) *IN GENERAL.*—Not later than 18 months
5 after the date of enactment of this Act, the Comp-
6 troller General of the United States shall submit to
7 the Committee on Health, Education, Labor, and
8 Pensions of the Senate and the Committee on Energy
9 and Commerce of the House of Representatives, a re-
10 port assessing the policies, practices, and programs of
11 the Food and Drug Administration with respect to
12 the review of applications for drugs and biological
13 products intended to treat rare diseases and condi-
14 tions (as defined in section 526(a)(2) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 360bb(a)(2))).

17 (2) *CONTENT OF REPORT.*—The report under
18 paragraph (1) shall—

19 (A) describe the activities of the Food and
20 Drug Administration dedicated to the develop-
21 ment and review of drugs and biological prod-
22 ucts intended to treat rare diseases and condi-
23 tions;

24 (B) describe challenges with developing and
25 obtaining approval or licensure of drugs and bio-
26 logical products intended to treat rare diseases

1 *and conditions, such as challenges related to de-*
2 *signing and conducting clinical trials, clinical*
3 *trial subject recruitment and enrollment, study*
4 *endpoints, and ensuring data quality, assessing*
5 *the benefit-risk profile of drugs and biological*
6 *products intended to treat rare diseases and con-*
7 *ditions, and meeting requirements for approval*
8 *or licensure;*

9 *(C) assess the effectiveness of policies and*
10 *practices of the Food and Drug Administration*
11 *related to the review of applications for drugs*
12 *and biological products intended to treat rare*
13 *diseases and conditions, including—*

14 *(i) initiatives to support the develop-*
15 *ment and review of drugs and biological*
16 *products intended to treat rare diseases and*
17 *conditions, including initiatives related to*
18 *regulatory science, clinical trial design, sta-*
19 *tistical analysis, and other relevant topics;*

20 *(ii) consideration of relevant patient-*
21 *focused drug development data and infor-*
22 *mation, including patient experience data*
23 *and the views of patients, pursuant to sec-*
24 *tion 569C of the Federal Food, Drug, and*
25 *Cosmetic Act (21 U.S.C. 360bbb–8c);*

1 (iii) training and other efforts to en-
2 sure the expertise of personnel of the Food
3 and Drug Administration regarding the re-
4 view of applications for drugs and biologi-
5 cal products intended to treat rare diseases
6 and conditions; and

7 (iv) consultations and engagement with
8 stakeholders, including patients and patient
9 groups, and external experts pursuant to
10 section 569 of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 360bbb–8);

12 (D) assess the extent to which the Food and
13 Drug Administration is applying the policies
14 and practices described in subparagraph (C)
15 consistently across review divisions, and the fac-
16 tors that influence the extent to which such ap-
17 plication is consistent; and

18 (E) include recommendations to address
19 challenges and deficiencies identified, including
20 recommendations to improve the effectiveness,
21 consistency, and coordination of policies, prac-
22 tices, and programs of the Food and Drug Ad-
23 ministration related to the review of applications
24 for drugs and biological products intended to
25 treat rare diseases and conditions.

1 ***(b) FDA REPORT.—***

2 ***(1) IN GENERAL.—****Not later than March 31,*
3 *2026, the Secretary of Health and Human Services*
4 *(referred to in this subsection as the “Secretary”)*
5 *shall submit to the Committee on Health, Education,*
6 *Labor, and Pensions of the Senate and the Committee*
7 *on Energy and Commerce of the House of Representa-*
8 *tives a report assessing the policies, practices, and*
9 *programs of the Food and Drug Administration with*
10 *respect to the review of applications for drugs and bi-*
11 *ological products intended to treat rare diseases and*
12 *conditions (as defined in section 526(a)(2) of the Fed-*
13 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
14 *360bb(a)(2))).*

15 ***(2) CONTENT OF REPORT.—****The report under*
16 *paragraph (1) shall include, with respect to the pe-*
17 *riod of fiscal years 2023 through 2025, broken down*
18 *by fiscal year and by the responsible review division*
19 *of the Food and Drug Administration—*

20 ***(A)*** *the number of drugs that have been des-*
21 *ignated as a drug for a rare disease or condition*
22 *under section 526 of the Federal Food, Drug,*
23 *and Cosmetic Act (21 U.S.C. 360bb);*

24 ***(B)*** *the number of applications under sec-*
25 *tion 505(b) of the Federal Food, Drug, and Cos-*

1 *metic Act (21 U.S.C. 355(b)) or section 351(a) of*
2 *the Public Health Service Act (42 U.S.C. 262(a))*
3 *for a drug designated under section 526 for a*
4 *rare disease or condition that were submitted,*
5 *the number of such applications that were ap-*
6 *proved, and the approximate size of the affected*
7 *population in the United States upon which the*
8 *designation pursuant to section 526 of the Fed-*
9 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
10 *360bb) was granted for each such submitted and*
11 *approved application;*

12 *(C) the number of applications for a drug*
13 *or biological product for which the sponsor re-*
14 *quested written recommendations pursuant to*
15 *section 525 of the Federal Food, Drug, and Cos-*
16 *metic Act (21 U.S.C. 360aa), and the number of*
17 *such applications for which the sponsor received*
18 *such written recommendations;*

19 *(D) the number of applications for which*
20 *the Secretary consulted patients and patient*
21 *groups pursuant to subsection (a)(1) of section*
22 *569 of the Federal Food, Drug, and Cosmetic Act*
23 *(21 U.S.C. 360bbb–8) and the number of appli-*
24 *cations for which the Secretary consulted experts*

1 *pursuant to subsection (a)(2) of such section 569;*
 2 *and*

3 *(E) the number of applications for which*
 4 *the Secretary allowed the sponsor to rely upon*
 5 *data and information pursuant to section 529A*
 6 *of the Federal Food, Drug, and Cosmetic Act (21*
 7 *U.S.C. 360ff–1).*

8 *(3) CLARIFICATION.—Nothing in this subsection*
 9 *shall be construed to authorize the disclosure of con-*
 10 *fidential commercial information or other informa-*
 11 *tion considered proprietary or trade secret, as prohib-*
 12 *ited under section 301(j) of the Federal Food, Drug,*
 13 *and Cosmetic Act (21 U.S.C. 331(j)) or section 1905*
 14 *of title 18, United States Code.*

15 *(c) GUIDANCE.—Not later than 9 months after the date*
 16 *of enactment of this Act, the Secretary shall publish final*
 17 *guidance related to the draft guidance titled, “Rare Dis-*
 18 *eases: Common Issues in Drug Development” issued on Feb-*
 19 *ruary 1, 2019.*

20 *(d) REVIEW PROCESS.—*

21 *(1) CONSULTATION WITH STAKEHOLDERS.—Sec-*
 22 *tion 569(a)(1) of the Federal Food, Drug, and Cos-*
 23 *metic Act (21 U.S.C. 360bbb–8(a)(1)) is amended—*

24 *(A) by striking “at a time” and inserting*
 25 *“at any time”;*

1 (B) by striking “Consistent with sections”
2 and inserting the following:

3 “(A) *IN GENERAL.*—Consistent with sec-
4 tions”; and

5 (C) by adding at the end the following:

6 “(B) *CONSULTATION WITH PATIENTS AND*
7 *PATIENT GROUPS.*—

8 “(i) *IN GENERAL.*—The Secretary may,
9 as appropriate, consult with patients and
10 relevant patient groups impacted by the
11 rare disease or condition, together with at
12 least one expert included on the list under
13 paragraph (2)(A) and selected by such
14 groups, as applicable, during meetings be-
15 tween the Food and Drug Administration
16 and sponsors prior to the submission of an
17 application for a new drug or biological
18 product for a rare disease or condition or a
19 drug or biological product that is geneti-
20 cally targeted.

21 “(ii) *CONFLICTS OF INTEREST.*—For
22 purposes of clause (i), to be eligible for con-
23 sultation pursuant to clause (i), patients
24 and relevant patient groups may not have
25 any financial interest in the applicable

1 *drug or biological product, and external ex-*
 2 *perts shall be in compliance with applicable*
 3 *law, including section 208 of title 18,*
 4 *United States Code.*

5 “(C) *CONSULTATION WITH DISPROPORTION-*
 6 *ATELY AFFECTED COMMUNITIES.—To the extent*
 7 *an application for a new drug or biological*
 8 *product relates to a rare disease or condition*
 9 *that disproportionately affects communities of*
 10 *color or other historically underrepresented and*
 11 *vulnerable populations, the Secretary is encour-*
 12 *aged to consult with patients of that subpopula-*
 13 *tion, or one or more patient groups that rep-*
 14 *resent that subpopulation.”.*

15 (2) *REQUIRING APPROPRIATE EXPERT CON-*
 16 *SULTATION.—Section 569(a)(2) of the Federal Food,*
 17 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–8(a)(2))*
 18 *is amended—*

19 (A) *in subparagraph (A), by striking the*
 20 *second sentence; and*

21 (B) *by striking subparagraph (B) and in-*
 22 *serting the following:*

23 “(B) *CONSULTATION.—With respect to any*
 24 *application under section 505 of this Act or sec-*
 25 *tion 351 of the Public Health Service Act for a*

1 *drug designated under section 526 for a rare dis-*
 2 *ease or condition or a drug or biological product*
 3 *that is genetically targeted, the Secretary may,*
 4 *as appropriate, consult—*

5 “(i) *with an expert with respect to the*
 6 *disease or condition referenced in the appli-*
 7 *cation who appears on the list described in*
 8 *subparagraph (A); or*

9 “(ii) *if no such expert is available, in-*
 10 *cluding because of conflicts of interest, with*
 11 *an expert on the list described in subpara-*
 12 *graph (A) in the science of small population*
 13 *studies.*

14 “(C) *AVAILABILITY AT MEETINGS.—In con-*
 15 *nection with each drug product advisory com-*
 16 *mittee meeting concerning a drug or biological*
 17 *product for a rare disease or condition, the Sec-*
 18 *retary may, as appropriate—*

19 “(i) *include—*

20 “(I) *an expert in the rare disease*
 21 *or condition; or*

22 “(II) *if no such expert is avail-*
 23 *able, including because of conflicts of*
 24 *interest, an expert in the science of*
 25 *small population studies; and*

1 “(ii) invite at least one disease or con-
 2 dition expert identified by the relevant pa-
 3 tient groups to participate as a nonvoting
 4 member of the advisory committee.”.

5 (3) *ADDITIONAL TOPIC FOR CONSULTATION.*—
 6 Section 569(b) of the Federal Food, Drug, and Cos-
 7 metic Act (21 U.S.C. 360bbb–8(b)) is amended—

8 (A) in paragraph (6), by striking “; and”
 9 and inserting “;”;

10 (B) in paragraph (7), by striking the period
 11 and inserting “; and”; and

12 (C) by adding at the end the following:

13 “(8) the science of small population studies.”.

14 **SEC. 509. GENERIC DRUG LABELING CHANGES.**

15 Section 505(j)(10)(A) of the Federal Food, Drug, and
 16 Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended by
 17 striking clauses (i) through (iii) and inserting the following:

18 “(i) a revision to the labeling of the listed drug
 19 has been approved by the Secretary within 90 days
 20 of when the application is otherwise eligible for ap-
 21 proval under this subsection;

22 “(ii) the sponsor of the application agrees to sub-
 23 mit revised labeling for the drug that is the subject of
 24 the application not later than 60 days after approval
 25 under this subsection of the application;

1 “(iii) the labeling revision described under clause
2 (i) does not include a change to the ‘Warnings’ sec-
3 tion of the labeling; and”.

4 **SEC. 510. LIMITATIONS ON EXCLUSIVE APPROVAL OR LI-**
5 **CENSURE OF ORPHAN DRUGS.**

6 (a) *IN GENERAL.*—Section 527 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—
8 (1) in subsection (a), in the matter following
9 paragraph (2), by striking “same disease or condi-
10 tion” and inserting “same approved use or indication
11 within such rare disease or condition”;

12 (2) in subsection (b)—

13 (A) in the matter preceding paragraph (1),
14 by striking “same rare disease or condition” and
15 inserting “same approved use or indication for
16 which such 7-year period applies to such already
17 approved drug”; and

18 (B) in paragraph (1), by inserting “, relat-
19 ing to the approved use or indication,” after “the
20 needs”;

21 (3) in subsection (c)(1), by striking “same rare
22 disease or condition as the already approved drug”
23 and inserting “same use or indication for which the
24 already approved or licensed drug was approved or
25 licensed”; and

1 (4) *by adding at the end the following:*

2 “(f) *APPROVED USE OR INDICATION DEFINED.*—In
3 *this section, the term ‘approved use or indication’ means*
4 *the use or indication approved under section 505 of this*
5 *Act or licensed under section 351 of the Public Health Serv-*
6 *ice Act for a drug designated under section 526 for a rare*
7 *disease or condition.”.*

8 (b) *APPLICATION OF AMENDMENTS.*—*The amendments*
9 *made by subsection (a) shall apply with respect to any drug*
10 *designated under section 526 of the Federal Food, Drug,*
11 *and Cosmetic Act (21 U.S.C. 360bb), regardless of the date*
12 *on which the drug was so designated, and regardless of the*
13 *date on which the drug was approved under section 505*
14 *of such Act (21 U.S.C. 355) or licensed under section 351*
15 *of the Public Health Service Act (42 U.S.C. 262).*

16 **SEC. 511. ENSURING TIMELY ACCESS TO GENERICS.**

17 *Section 505(q) of the Federal Food, Drug, and Cos-*
18 *metic Act (21 U.S.C. 355(q)) is amended—*

19 (1) *in paragraph (1)—*

20 (A) *in subparagraph (A)(i), by inserting “,*
21 *10.31,” after “10.30”;*

22 (B) *in subparagraph (E)—*

23 (i) *by striking “application and” and*
24 *inserting “application or”;*

1 (ii) by striking “If the Secretary” and
2 inserting the following:

3 “(i) *IN GENERAL.—If the Secretary*”;
4 and

5 (iii) by striking the second sentence
6 and inserting the following:

7 “(ii) *PRIMARY PURPOSE OF DELAY-*
8 *ING.—*

9 “(I) *IN GENERAL.—In deter-*
10 *mining whether a petition was sub-*
11 *mitted with the primary purpose of de-*
12 *laying an application, the Secretary*
13 *may consider the following factors:*

14 “(aa) *Whether the petition*
15 *was submitted in accordance with*
16 *paragraph (2)(B), based on when*
17 *the petitioner knew or reasonably*
18 *should have known the relevant*
19 *information relied upon to form*
20 *the basis of such petition.*

21 “(bb) *Whether the petitioner*
22 *has submitted multiple or serial*
23 *petitions or supplements to peti-*
24 *tions raising issues that reason-*
25 *ably could have been known to the*

1 petitioner at the time of submis-
2 sion of the earlier petition or peti-
3 tions.

4 “(cc) Whether the petition
5 was submitted close in time to a
6 known, first date upon which an
7 application under subsection
8 (b)(2) or (j) of this section or sec-
9 tion 351(k) of the Public Health
10 Service Act could be approved.

11 “(dd) Whether the petition
12 was submitted without relevant
13 data or information in support of
14 the scientific positions forming the
15 basis of such petition.

16 “(ee) Whether the petition
17 raises the same or substantially
18 similar issues as a prior petition
19 to which the Secretary has re-
20 sponded substantively already, in-
21 cluding if the subsequent submis-
22 sion follows such response from
23 the Secretary closely in time.

24 “(ff) Whether the petition re-
25 quests changing the applicable

standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner's version of the same drug.

“(gg) The petitioner's record of submitting petitions to the Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.

“(hh) Other relevant and appropriate factors, which the Secretary shall describe in guidance.

“(II) GUIDANCE.—The Secretary may issue or update guidance, as appropriate, to describe factors the Secretary considers in accordance with subclause (I).”;

(C) by adding at the end the following:

1 “(iii) *REFERRAL TO THE FEDERAL*
 2 *TRADE COMMISSION.—The Secretary shall*
 3 *establish procedures for referring to the Fed-*
 4 *eral Trade Commission any petition or sup-*
 5 *plement to a petition that the Secretary de-*
 6 *termines was submitted with the primary*
 7 *purpose of delaying approval of an applica-*
 8 *tion. Such procedures shall include notifica-*
 9 *tion to the petitioner by the Secretary.”;*

10 *(D) by striking subparagraph (F);*

11 *(E) by redesignating subparagraphs (G)*
 12 *through (I) as subparagraphs (F) through (H),*
 13 *respectively; and*

14 *(F) in subparagraph (H), as so redesign-*
 15 *ated, by striking “submission of this petition”*
 16 *and inserting “submission of this document”;*

17 *(2) in paragraph (2)—*

18 *(A) by redesignating subparagraphs (A)*
 19 *through (C) as subparagraphs (C) through (E),*
 20 *respectively;*

21 *(B) by inserting before subparagraph (C),*
 22 *as so redesignated, the following:*

23 *“(A) IN GENERAL.—A person shall submit a*
 24 *petition to the Secretary under paragraph (1)*
 25 *before filing a civil action in which the person*

1 *seeks to set aside, delay, rescind, withdraw, or*
 2 *prevent submission, review, or approval of an*
 3 *application submitted under subsection (b)(2) or*
 4 *(j) of this section or section 351(k) of the Public*
 5 *Health Service Act. Such petition and any sup-*
 6 *plement to such a petition shall describe all in-*
 7 *formation and arguments that form the basis of*
 8 *the relief requested in any civil action described*
 9 *in the previous sentence.*

10 “(B) *TIMELY SUBMISSION OF CITIZEN PETI-*
 11 *TION.—A petition and any supplement to a peti-*
 12 *tion shall be submitted within 60 days after the*
 13 *person knew, or reasonably should have known,*
 14 *the information that forms the basis of the re-*
 15 *quest made in the petition or supplement.”;*

16 (C) *in subparagraph (C), as so redesign-*
 17 *ated—*

18 (i) *in the heading, by striking “WITHIN*
 19 *150 DAYS”;*

20 (ii) *in clause (i), by striking “during*
 21 *the 150-day period referred to in paragraph*
 22 *(1)(F),”;* and

23 (iii) *by amending clause (ii) to read as*
 24 *follows:*

1 “(ii) on or after the date that is 151
 2 days after the date of submission of the peti-
 3 tion, the Secretary approves or has ap-
 4 proved the application that is the subject of
 5 the petition without having made such a
 6 final decision.”;

7 (D) by amending subparagraph (D), as so
 8 redesignated, to read as follows:

9 “(D) *DISMISSAL OF CERTAIN CIVIL AC-*
 10 *TIONS.—*

11 “(i) *PETITION.—*If a person files a
 12 civil action against the Secretary in which
 13 a person seeks to set aside, delay, rescind,
 14 withdraw, or prevent submission, review, or
 15 approval of an application submitted under
 16 subsection (b)(2) or (j) of this section or sec-
 17 tion 351(k) of the Public Health Service Act
 18 without complying with the requirements of
 19 subparagraph (A), the court shall dismiss
 20 without prejudice the action for failure to
 21 exhaust administrative remedies.

22 “(ii) *TIMELINESS.—*If a person files a
 23 civil action against the Secretary in which
 24 a person seeks to set aside, delay, rescind,
 25 withdraw, or prevent submission, review, or

1 approval of an application submitted under
 2 subsection (b)(2) or (j) of this section or sec-
 3 tion 351(k) of the Public Health Service Act
 4 without complying with the requirements of
 5 subparagraph (B), the court shall dismiss
 6 with prejudice the action for failure to time-
 7 ly file a petition.

8 “(iii) *FINAL RESPONSE*.—If a civil ac-
 9 tion is filed against the Secretary with re-
 10 spect to any issue raised in a petition time-
 11 ly filed under paragraph (1) in which the
 12 petitioner requests that the Secretary take
 13 any form of action that could, if taken, set
 14 aside, delay, rescind, withdraw, or prevent
 15 submission, review, or approval of an appli-
 16 cation submitted under subsection (b)(2) or
 17 (j) of this section or section 351(k) of the
 18 Public Health Service Act before the Sec-
 19 retary has taken final agency action on the
 20 petition within the meaning of subpara-
 21 graph (C), the court shall dismiss without
 22 prejudice the action for failure to exhaust
 23 administrative remedies.”; and

24 (E) in clause (iii) of subparagraph (E), as
 25 so redesignated, by striking “as defined under

1 subparagraph (2)(A)” and inserting “within the
 2 meaning of subparagraph (C)”;
 3 (3) in paragraph (4)—

4 (A) by striking “EXCEPTIONS” and all that
 5 follows through “This subsection does” and in-
 6 serting “EXCEPTIONS.—This subsection does”;

7 (B) by striking subparagraph (B); and

8 (C) by redesignating clauses (i) and (ii) as
 9 subparagraphs (A) and (B), respectively, and
 10 adjusting the margins accordingly.

11 **SEC. 512. INCREASING TRANSPARENCY IN GENERIC DRUG**
 12 **APPLICATIONS.**

13 (a) *IN GENERAL.*—Section 505(j)(3) of the Federal
 14 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is
 15 amended by adding at the end the following:

16 “(H)(i) Upon request (in controlled correspondence or
 17 otherwise) by a person that has submitted or intends to sub-
 18 mit an abbreviated application under this subsection for
 19 a drug that is generally required by regulation or rec-
 20 ommended in guidance to contain the same inactive ingre-
 21 dients in the same concentration as the listed drug referred
 22 to or for which there is a scientific justification that an
 23 *in vitro* approach can be used to demonstrate bioequivalence
 24 based on certain qualitative or quantitative criteria with
 25 respect to an inactive ingredient, or on the Secretary’s own

1 *initiative during the review of an application under this*
2 *subsection for such a drug, the Secretary shall inform the*
3 *person whether such drug is qualitatively and quan-*
4 *titatively the same as the listed drug.*

5 “(ii) *If the Secretary determines that such drug is not*
6 *qualitatively or quantitatively the same as the listed drug,*
7 *the Secretary shall identify and disclose to the person—*

8 “(I) *the ingredient or ingredients that cause the*
9 *drug not to be qualitatively or quantitatively the*
10 *same as the listed drug; and*

11 “(II) *for any ingredient for which there is an*
12 *identified quantitative deviation, the amount of such*
13 *deviation.*

14 “(iii) *If the Secretary determines that such drug is*
15 *qualitatively and quantitatively the same as the listed drug,*
16 *the Secretary shall not change or rescind such determina-*
17 *tion after the submission of an abbreviated application for*
18 *such drug under this subsection unless—*

19 “(I) *the formulation of the listed drug has been*
20 *changed and the Secretary has determined that the*
21 *prior listed drug formulation was withdrawn for rea-*
22 *sons of safety or effectiveness; or*

23 “(II) *the Secretary makes a written determina-*
24 *tion that the prior determination must be changed be-*
25 *cause an error has been identified.*

1 “(iv) *If the Secretary makes a written determination*
 2 *described in clause (iii)(II), the Secretary shall provide no-*
 3 *tice and a copy of the written determination to the person*
 4 *making the request under clause (i).*

5 “(v) *The disclosures required by this subparagraph are*
 6 *disclosures authorized by law, including for purposes of sec-*
 7 *tion 1905 of title 18, United States Code.”.*

8 (b) *GUIDANCE.—*

9 (1) *IN GENERAL.—Not later than one year after*
 10 *the date of enactment of this Act, the Secretary of*
 11 *Health and Human Services shall issue draft guid-*
 12 *ance, or update guidance, describing how the Sec-*
 13 *retary will determine whether a drug is qualitatively*
 14 *and quantitatively the same as the listed drug (as*
 15 *such terms are used in section 505(j)(3)(H) of the*
 16 *Federal Food, Drug, and Cosmetic Act, as added by*
 17 *subsection (a)), including with respect to assessing*
 18 *pH adjusters.*

19 (2) *PROCESS.—In issuing guidance under this*
 20 *subsection, the Secretary of Health and Human Serv-*
 21 *ices shall—*

22 (A) *publish draft guidance;*

23 (B) *provide a period of at least 60 days for*
 24 *comment on the draft guidance; and*

1 (C) after considering any comments received
 2 and not later than one year after the close of the
 3 comment period on the draft guidance, publish
 4 final guidance.

5 (c) *APPLICABILITY.*—Section 505(j)(3)(H) of the Fed-
 6 eral Food, Drug, and Cosmetic Act, as added by subsection
 7 (a), applies beginning on the date of enactment of this Act,
 8 irrespective of the date on which the guidance required by
 9 subsection (b) is finalized.

10 **SEC. 513. GAO REPORT ON NONPROFIT PHARMACEUTICAL**
 11 **ORGANIZATIONS.**

12 (a) *GAO REVIEW.*—The Comptroller General of the
 13 United States (referred to in this section as the “Comp-
 14 troller General”) shall prepare a report on—

15 (1) what is known about nonprofit pharma-
 16 ceutical manufacturing organizations, including the
 17 impact of such organizations on the development,
 18 availability, and cost of prescription drugs in the
 19 United States, which may include information with
 20 respect to the capacity and capability to help prevent
 21 or mitigate shortages of such drugs, and any chal-
 22 lenges to manufacturing or other operations; and

23 (2) recommendations to address such challenges.

24 (b) *REPORT.*—Not later than 2 years after the date
 25 of enactment of this Act, the Comptroller General shall sub-

1 *mit the report described in subsection (a) to the Committee*
2 *on Health, Education, Labor, and Pensions of the Senate*
3 *and the Committee on Energy and Commerce of the House*
4 *of Representatives.*

5 **SEC. 514. FDA PUBLIC MEETING ON NONPROFIT PRESCRIP-**
6 **TION DRUG MANUFACTURERS.**

7 *(a) IN GENERAL.—Not later than 1 year after the date*
8 *of enactment of this Act, the Secretary of Health and*
9 *Human Services shall—*

10 *(1) hold a public meeting on nonprofit manufac-*
11 *turers of prescription drugs, which shall include pub-*
12 *lic testimony from relevant stakeholders and aca-*
13 *demics; and*

14 *(2) open a docket for public comment related to*
15 *such meeting.*

16 *(b) TOPICS.—The public meeting under subsection (a)*
17 *shall focus on the following topics:*

18 *(1) The extent to which growth in the nonprofit*
19 *prescription drug sector can help address patient ac-*
20 *cess challenges in the current prescription drug mar-*
21 *ketplace, such as drug shortages, limited medication*
22 *alternatives and competition, supply chain resiliency,*
23 *and specific products where there is insufficient mar-*
24 *ket demand to induce manufacturers to continue to*
25 *offer certain prescription drugs.*

1 (2) *Whether, and to what extent, the Secretary of*
 2 *Health and Human Services should consider changes*
 3 *to future user fee structures and processes for non-*
 4 *profit manufacturers of prescription drugs.*

5 **SEC. 515. 180-DAY EXCLUSIVITY PERIOD.**

6 (a) *IN GENERAL.*—Section 505(j)(5)(B)(iv) of the Fed-
 7 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 8 *355(j)(5)(B)(iv)) is amended—*

9 (1) *in subclause (I)—*

10 (A) *by inserting “and subclause (III)” after*
 11 *“subparagraph (D)”;* and

12 (B) *by inserting before the period at the end*
 13 *the following: “or an applicant whose applica-*
 14 *tion was approved pursuant to subclause (III).*
 15 *If an applicant described in subclause (III) is el-*
 16 *igible for effective approval on the same day a*
 17 *tentatively approved first applicant who has re-*
 18 *quested final approval is determined by the Sec-*
 19 *retary to be eligible for effective approval by*
 20 *meeting all the approval requirements of this*
 21 *subsection, such applicant may not receive effec-*
 22 *tive approval until 180 days after the first ap-*
 23 *plicant begins commercial marketing of the*
 24 *drug.”;* and

1 (2) by adding at the end the following new sub-
2 *clause:*

3 “(III) *APPLICANT APPROVAL.*—The Sec-
4 *retary may approve an application containing a*
5 *certification described in paragraph*
6 *(2)(A)(vii)(IV) that is for a drug for which a*
7 *first applicant has submitted an application*
8 *containing such a certification, notwithstanding*
9 *the eligibility of a first applicant for the 180-day*
10 *exclusivity period described in subclause*
11 *(II)(aa), if each of the following conditions is*
12 *met:*

13 “(aa) *The approval of such application*
14 *could be made effective, but for the eligi-*
15 *bility of a first applicant for 180-day exclu-*
16 *sivity under this clause.*

17 “(bb) *The applicant of such applica-*
18 *tion has submitted a certification to the ab-*
19 *breivated new drug application that there*
20 *are no conditions that would prevent the*
21 *applicant from commercial marketing with-*
22 *in 75 days after the date of approval and*
23 *that the applicant intends to so market the*
24 *drug.*

1 “(cc) *At least 33 months have passed*
 2 *since the date of submission of an applica-*
 3 *tion for the drug by at least one first appli-*
 4 *cant.*

5 “(dd) *Approval of an application for*
 6 *the drug submitted by at least one first ap-*
 7 *plicant is not precluded under clause (iii).*

8 “(ee) *No application for the drug sub-*
 9 *mitted by any first applicant is effectively*
 10 *approved on the date that the conditions*
 11 *under items (aa), (bb), (cc), and (dd) are*
 12 *all met and maintained.”.*

13 (b) *SPECIAL APPROVAL STATUS RULE FOR CERTAIN*
 14 *SUBSEQUENT APPLICANTS.—Section 505(j)(5)(D) of the*
 15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355*
 16 *(j)(5)(D)) is amended at the end by adding the following:*

17 “(v) *SPECIAL APPROVAL STATUS RULE FOR*
 18 *CERTAIN SUBSEQUENT APPLICANTS.—An appli-*
 19 *cation that is approved pursuant to subclause*
 20 *(III) of subparagraph (B)(iv) is deemed to be*
 21 *tentatively approved and to no longer have an*
 22 *effective approval pursuant to such subclause*
 23 *(III) on the date that is 76 days after the date*
 24 *on which the approval has been made effective*
 25 *pursuant to such subclause (III) if the applicant*

1 *fails to commercially market such drug within*
2 *the 75-day period after the date on which the ap-*
3 *proval is made effective. If the applicant of an*
4 *application approved pursuant to such subclause*
5 *(III) submits a notification that it can no longer*
6 *commence commercial marketing within 75 days*
7 *after the date of approval, as required under sub-*
8 *paragraph (B)(iv)(III)(bb), its application is*
9 *deemed to be tentatively approved and to no*
10 *longer be effectively approved on the date that*
11 *such a notification is received. If an applicant*
12 *does not commence commercial marketing within*
13 *the 75-day period, it shall not be eligible for a*
14 *subsequent effective approval for the application*
15 *under subclause (III) of subparagraph (B)(iv)*
16 *unless, in addition to meeting each of the condi-*
17 *tions in such subclause (III), it submits a certifi-*
18 *cation to its abbreviated new drug application*
19 *that an event that could not have been reason-*
20 *ably foreseen by the applicant prevented it from*
21 *commencing commercial marketing and that it*
22 *has fully resolved this issue. The applicant shall*
23 *submit notification to the abbreviated new drug*
24 *application confirming that such applicant has*
25 *commenced commercial marketing of the drug*

1 *not later than one business day after com-*
 2 *mencing such marketing.”.*

3 (c) *APPLICABILITY.—The amendments made by sub-*
 4 *sections (a) and (b) shall apply only with respect to an*
 5 *application filed under section 505(j) of the Federal Food,*
 6 *Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date*
 7 *of enactment of this Act that identifies a listed drug for*
 8 *which no certification under paragraph (2)(A)(vii)(IV) of*
 9 *such section was made before such date of enactment.*

10 **TITLE VI—OTHER** 11 **REAUTHORIZATIONS**

12 **SEC. 601. REAUTHORIZATION OF THE CRITICAL PATH PUB-** 13 **LIC-PRIVATE PARTNERSHIP.**

14 *Section 566(f) of the Federal Food, Drug, and Cos-*
 15 *metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking*
 16 *“2018 through 2022” and inserting “2023 through 2027”.*

17 **SEC. 602. REAUTHORIZATION OF THE BEST PHARMA-** 18 **CEUTICALS FOR CHILDREN PROGRAM.**

19 *Section 409I(d)(1) of the Public Health Service Act*
 20 *(42 U.S.C. 284m(d)(1)) is amended by striking “2018*
 21 *through 2022” and inserting “2023 through 2027”.*

1 **SEC. 603. REAUTHORIZATION OF THE HUMANITARIAN DE-**
2 **VICE EXEMPTION INCENTIVE.**

3 *Section 520(m)(6)(A)(iv) of the Federal Food, Drug,*
4 *and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended*
5 *by striking “2022” and inserting “2027”.*

6 **SEC. 604. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
7 **CONSORTIA PROGRAM.**

8 *Section 305(e) of the Food and Drug Administration*
9 *Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.*
10 *282 note) is amended by striking “\$5,250,000 for each of*
11 *fiscal years 2018 through 2022” and inserting “\$7,000,000*
12 *for each of fiscal years 2023 through 2027”.*

13 **SEC. 605. REAUTHORIZATION OF PROVISION PERTAINING**
14 **TO DRUGS CONTAINING SINGLE**
15 **ENANTIOMERS.**

16 *Section 505(u) of the Federal Food, Drug, and Cos-*
17 *metic Act (21 U.S.C. 355(u)) is amended by—*

18 *(1) in paragraph (1)(A)(ii)(II), by adding*
19 *“(other than bioavailability studies)” after “any clin-*
20 *ical investigations”; and*

21 *(2) in paragraph (4), by striking “October 1,*
22 *2022” and inserting “October 1, 2027”.*

23 **SEC. 606. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

24 *Section 5(c) of the Orphan Drug Act (21 U.S.C.*
25 *360ee(c)) is amended by striking “2018 through 2022” and*
26 *inserting “2023 through 2027”.*

1 **SEC. 607. REAUTHORIZATION OF CERTAIN DEVICE INSPEC-**
 2 **TIONS.**

3 *Section 704(g)(11) of the Federal Food, Drug, and Cos-*
 4 *metic Act (21 U.S.C. 374(g)(11)) is amended by striking*
 5 *“2022” and inserting “2027”.*

6 **TITLE VII—ENHANCING FDA**
 7 **HIRING AUTHORITIES**

8 **SEC. 701. ENHANCING FDA HIRING AUTHORITY FOR SCI-**
 9 **ENTIFIC, TECHNICAL, AND PROFESSIONAL**
 10 **PERSONNEL.**

11 *Section 714A of the Federal Food, Drug, and Cosmetic*
 12 *Act (21 U.S.C. 379d–3a) is amended—*

13 *(1) in subsection (a)—*

14 *(A) by inserting “, including cross-cutting*
 15 *operational positions,” after “professional posi-*
 16 *tions”; and*

17 *(B) by inserting “and the regulation of*
 18 *food” after “medical products”; and*

19 *(2) in subsection (d)(1)—*

20 *(A) in the matter preceding subparagraph*
 21 *(A)—*

22 *(i) by striking “the 21st Century Cures*
 23 *Act” and inserting “the Food and Drug Ad-*
 24 *ministration Safety and Landmark Ad-*
 25 *vancements Act of 2022”; and*

1 (ii) by striking “that examines the ex-
2 tent” and all that follows through “, includ-
3 ing” and inserting “that addresses”;

4 (B) in subparagraph (A)—

5 (i) by inserting “updated” before
6 “analysis”; and

7 (ii) by striking “; and” and inserting
8 a semicolon;

9 (C) by redesignating subparagraph (B) as
10 subparagraph (C);

11 (D) by inserting after subparagraph (A) the
12 following:

13 “(B) an analysis of how the Secretary has
14 used the authorities provided under this section,
15 and a plan for how the Secretary will use the
16 authority under this section, and other applica-
17 ble hiring authorities, for employees of the Food
18 and Drug Administration; and”; and

19 (E) in the matter preceding clause (i) of
20 subparagraph (C), as so redesignated, by striking
21 “a recruitment” and inserting “an updated re-
22 cruitment”.

1 **SEC. 702. STRATEGIC WORKFORCE PLAN AND REPORT.**

2 *Chapter VII of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 371 et seq.) is amended by inserting after*
4 *section 714A the following:*

5 **“SEC. 714B. STRATEGIC WORKFORCE PLAN AND REPORT.**

6 *“(a) IN GENERAL.—Not later than September 30,*
7 *2023, and at least every 4 years thereafter, the Secretary*
8 *shall develop and submit to the appropriate committees of*
9 *Congress and post on the website of the Food and Drug Ad-*
10 *ministration, a coordinated strategy and report to provide*
11 *direction for the activities and programs of the Secretary*
12 *to recruit, hire, train, develop, and retain the workforce*
13 *needed to fulfill the public health mission of the Food and*
14 *Drug Administration, including to facilitate collaboration*
15 *across centers, to keep pace with new biomedical, techno-*
16 *logical, and scientific advancements, and support the devel-*
17 *opment, review, and regulation of medical products. Each*
18 *such report shall be known as the ‘Food and Drug Adminis-*
19 *tration Strategic Workforce Plan’.*

20 *“(b) USE OF THE FOOD AND DRUG ADMINISTRATION*
21 *STRATEGIC WORKFORCE PLAN.—Each center within the*
22 *Food and Drug Administration shall develop and update,*
23 *as appropriate, a strategic plan that will be informed by*
24 *the Food and Drug Administration Strategic Workforce*
25 *Plan developed and updated under this subsection.*

1 “(c) *CONTENTS OF THE FOOD AND DRUG ADMINISTRA-*
2 *TION STRATEGIC WORKFORCE PLAN.*—Each Food and
3 *Drug Administration Strategic Workforce Plan* under sub-
4 *section (a) shall—*

5 “(1) *include agency-wide strategic goals and pri-*
6 *orities for recruiting, hiring, training, developing,*
7 *and retaining a qualified workforce for the Food and*
8 *Drug Administration;*

9 “(2) *establish specific activities the Secretary*
10 *will take to achieve its strategic goals and priorities*
11 *and address the workforce needs of the Food and Drug*
12 *Administration in the forthcoming fiscal years;*

13 “(3) *identify challenges and risks the Secretary*
14 *will face in meeting its strategic goals and priorities,*
15 *and the activities the Secretary will undertake to*
16 *overcome those challenges and mitigate those risks;*

17 “(4) *establish metrics and milestones that the*
18 *Secretary will use to measure progress in achieving*
19 *its strategic goals and priorities; and*

20 “(5) *define functions, capabilities, and gaps in*
21 *such workforce and identify strategies to recruit, hire,*
22 *train, develop, and retain such workforce.*

23 “(d) *CONSIDERATIONS.*—In developing each Food and
24 *Drug Administration Strategic Workforce Plan* under sub-
25 *section (a), the Secretary shall consider—*

1 “(1) the number of employees, employee exper-
2 tise, and employing center of employees, including
3 senior leadership and non-senior leadership employ-
4 ees, eligible for retirement;

5 “(2) the vacancy and turnover rates for employ-
6 ees with different types of expertise and from different
7 centers, including any changes or trends related to
8 such rates;

9 “(3) the results of the Federal Employee View-
10 point Survey for employees of the Food and Drug Ad-
11 ministration, including any changes or trends related
12 to such results;

13 “(4) rates of pay for different types of positions,
14 including rates for different types of expertise within
15 the same field (such as differences in pay between dif-
16 ferent medical specialists), and how such rates of pay
17 impact the ability of the Secretary to achieve strategic
18 goals and priorities; and

19 “(5) the statutory hiring authorities used to hire
20 Food and Drug Administration employees, and the
21 time to hire across different hiring authorities.

22 “(e) EVALUATION OF PROGRESS.—Each Food and
23 Drug Administration Strategic Workforce Plan issued pur-
24 suant to subsection (a), with the exception of the first such
25 Food and Drug Administration Strategic Workforce Plan,

1 *shall include an evaluation of the progress the Secretary*
 2 *has made, based on the metrics, benchmarks, and other*
 3 *milestones that measure successful recruitment, hiring,*
 4 *training, development, and retention activities; and wheth-*
 5 *er such actions improved the capacity of the Food and Drug*
 6 *Administration to achieve the strategic goals and priorities*
 7 *set forth in the previous Food and Drug Administration*
 8 *Strategic Workforce Plan.*

9 “(f) *ADDITIONAL CONSIDERATIONS.—The Food and*
 10 *Drug Administration Strategic Workforce Plan issued in*
 11 *fiscal year 2023 shall address the effect of the COVID–19*
 12 *pandemic on hiring, retention, and other workforce chal-*
 13 *lenges for the Food and Drug Administration, including*
 14 *protecting such workforce during public health emer-*
 15 *gencies.*”.

16 ***TITLE VIII—ADVANCING REGU-***
 17 ***LATION OF COSMETICS, DIE-***
 18 ***TARY SUPPLEMENTS, AND IN***
 19 ***VITRO CLINICAL TESTS***

20 ***Subtitle A—Cosmetics***

21 ***SEC. 801. SHORT TITLE.***

22 *This subtitle may be cited as the “Modernization of*
 23 *Cosmetics Regulation Act of 2022”.*

1 **SEC. 802. AMENDMENTS TO COSMETIC REQUIREMENTS.**

2 *Chapter VI of the Federal Food, Drug, and Cosmetic*
 3 *Act (21 U.S.C. 361 et seq.) is amended by adding at the*
 4 *end the following:*

5 **“SEC. 604. DEFINITIONS.**

6 *“In this chapter:*

7 *“(1) ADVERSE EVENT.—The term ‘adverse event’*
 8 *means any health-related event associated with the*
 9 *use of a cosmetic product that is adverse.*

10 *“(2) COSMETIC PRODUCT.—The term ‘cosmetic*
 11 *product’ means a preparation of cosmetic ingredients*
 12 *with a qualitatively and quantitatively set composi-*
 13 *tion for use in a finished product.*

14 *“(3) FACILITY.—*

15 *“(A) IN GENERAL.—The term ‘facility’ in-*
 16 *cludes any establishment (including an establish-*
 17 *ment of an importer) that manufactures or proc-*
 18 *esses cosmetic products distributed in the United*
 19 *States.*

20 *“(B) Such term does not include any of the*
 21 *following:*

22 *“(i) Beauty shops and salons, unless*
 23 *such establishment manufactures or proc-*
 24 *esses cosmetic products at that location.*

25 *“(ii) Cosmetic product retailers, in-*
 26 *cluding individual sales representatives, di-*

1 *rect sellers (as defined in section 3508(b)(2)*
2 *of the Internal Revenue Code of 1986), re-*
3 *tail distribution facilities, and pharmacies,*
4 *unless such establishment manufactures or*
5 *processes cosmetic products that are not sold*
6 *directly to consumers at that location.*

7 “(iii) *Hospitals, physicians’ offices,*
8 *and health care clinics.*

9 “(iv) *Public health agencies and other*
10 *nonprofit entities that provide cosmetic*
11 *products directly to the consumer.*

12 “(v) *Entities (such as hotels and air-*
13 *lines) that provide complimentary cosmetic*
14 *products to customers incidental to other*
15 *services.*

16 “(vi) *Trade shows and other venues*
17 *where cosmetic product samples are pro-*
18 *vided free of charge.*

19 “(vii) *An establishment that manufac-*
20 *tures or processes cosmetic products that are*
21 *solely for use in research or evaluation, in-*
22 *cluding for production testing and not of-*
23 *fered for retail sale.*

“(viii) *An establishment that solely performs one or more of the following with respect to cosmetic products:*

“(I) *Labeling.*

“(II) *Relabeling.*

“(III) *Packaging.*

“(IV) *Repackaging.*

“(V) *Holding.*

“(VI) *Distributing.*

“(C) *CLARIFICATION.—For the purposes of subparagraph (B)(viii), the terms ‘packaging’ and ‘repackaging’ do not include filling a product container with a cosmetic product.*

“(4) *RESPONSIBLE PERSON.—The term ‘responsible person’ means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of this Act or section 4(a) of the Fair Packaging and Labeling Act.*

“(5) *SERIOUS ADVERSE EVENT.—The term ‘serious adverse event’ means an adverse event that—*

“(A) *results in—*

“(i) *death;*

“(ii) *a life-threatening experience;*

“(iii) *inpatient hospitalization;*

1 “(iv) a persistent or significant dis-
2 ability or incapacity;

3 “(v) a congenital anomaly or birth de-
4 fect; or

5 “(vi) significant disfigurement (includ-
6 ing serious and persistent rashes or infec-
7 tions, second- or third-degree burns, signifi-
8 cant hair loss, or permanent or significant
9 alteration of appearance), other than as in-
10 tended, under conditions of use that are cus-
11 tomary or usual; or

12 “(B) requires, based on reasonable medical
13 judgment, a medical or surgical intervention to
14 prevent an outcome described in subparagraph
15 (A).

16 **“SEC. 605. ADVERSE EVENTS.**

17 “(a) *SERIOUS ADVERSE EVENT REPORTING REQUIRE-*
18 *MENTS.—The responsible person shall submit to the Sec-*
19 *retary any report received of a serious adverse event associ-*
20 *ated with the use, in the United States, of a cosmetic prod-*
21 *uct manufactured, packed, or distributed by such person.*

22 “(b) *SUBMISSION OF REPORTS.—*

23 “(1) *SERIOUS ADVERSE EVENT REPORT.—The*
24 *responsible person shall submit to the Secretary a se-*
25 *rious adverse event report accompanied by a copy of*

1 *the label on or within the retail packaging of such*
2 *cosmetic product no later than 15 business days after*
3 *the report is received by the responsible person.*

4 “(2) *NEW MEDICAL INFORMATION.*—*The respon-*
5 *sible person shall submit to the Secretary any new*
6 *and material medical information, related to a seri-*
7 *ous adverse event report submitted to the Secretary in*
8 *accordance with paragraph (1), that is received by the*
9 *responsible person within 1 year of the initial report*
10 *to the Secretary, no later than 15 business days after*
11 *such information is received by such responsible per-*
12 *son.*

13 “(3) *CONSOLIDATION OF REPORTS.*—*The Sec-*
14 *retary shall develop systems to enable responsible per-*
15 *sons to submit a single report that includes duplicate*
16 *reports of, or new medical information related to, a*
17 *serious adverse event.*

18 “(c) *EXEMPTIONS.*—*The Secretary may establish by*
19 *regulation an exemption to any of the requirements of this*
20 *section if the Secretary determines that such exemption*
21 *would have no significant adverse effect on public health.*

22 “(d) *CONTACT INFORMATION.*—*The responsible person*
23 *shall receive reports of adverse events through the domestic*
24 *address, domestic telephone number, or electronic contact*

1 *information included on the label in accordance with sec-*
 2 *tion 609(a).*

3 “(e) *MAINTENANCE AND INSPECTION OF ADVERSE*
 4 *EVENT RECORDS.*—

5 “(1) *MAINTENANCE.*—*The responsible person*
 6 *shall maintain records related to each report of an*
 7 *adverse event associated with the use, in the United*
 8 *States, of a cosmetic product manufactured or distrib-*
 9 *uted by such person received by such person, for a pe-*
 10 *riod of 6 years.*

11 “(2) *INSPECTION.*—

12 “(A) *IN GENERAL.*— *The responsible person*
 13 *shall permit an authorized person to have access*
 14 *to records required to be maintained under this*
 15 *section during an inspection pursuant to section*
 16 *704.*

17 “(B) *AUTHORIZED PERSON.*—*For purposes*
 18 *of this paragraph, the term ‘authorized person’*
 19 *means an officer or employee of the Department*
 20 *of Health and Human Services who has—*

21 “(i) *appropriate credentials, as deter-*
 22 *mined by the Secretary; and*

23 “(ii) *been duly designated by the Sec-*
 24 *retary to have access to the records required*
 25 *under this section.*

1 “(f) *FRAGRANCE AND FLAVOR INGREDIENTS.*—If the
 2 Secretary has reasonable grounds to believe that an ingre-
 3 dient or combination of ingredients in a fragrance or flavor
 4 has caused or contributed to a serious adverse event re-
 5 quired to be reported under this section, the Secretary may
 6 request in writing a list of ingredients or categories of in-
 7 gredients in the specific fragrances or flavors in the cosmetic
 8 product, from the responsible person. The responsible person
 9 shall ensure that the requested information is submitted to
 10 the Secretary within 30 days of such request. In response
 11 to a request under section 552 of title 5, United States Code,
 12 information submitted to the Secretary under this sub-
 13 section shall be withheld under section 552(b)(3) of title 5,
 14 United States Code.

15 “(g) *PROTECTED INFORMATION.*—A serious adverse
 16 event report submitted to the Secretary under this section,
 17 including any new medical information submitted under
 18 subsection (b)(2), or an adverse event report, or any new
 19 information, voluntarily submitted to the Secretary shall
 20 be considered to be—

21 “(1) a safety report under section 756 and may
 22 be accompanied by a statement, which shall be a part
 23 of any report that is released for public disclosure,
 24 that denies that the report or the records constitute an

1 *admission that the product involved caused or con-*
 2 *tributed to the adverse event; and*

3 *“(2) a record about an individual under section*
 4 *552a of title 5, United States Code (commonly re-*
 5 *ferred to as the ‘Privacy Act of 1974’) and a medical*
 6 *or similar file the disclosure of which would constitute*
 7 *a violation of section 552 of such title 5 (commonly*
 8 *referred to as the ‘Freedom of Information Act’), and*
 9 *shall not be publicly disclosed unless all personally*
 10 *identifiable information is redacted.*

11 *“(h) EFFECT OF SECTION.—*

12 *“(1) IN GENERAL.—Nothing in this section shall*
 13 *affect the authority of the Secretary to provide ad-*
 14 *verse event reports and information to any health,*
 15 *food, or drug officer or employee of any State, terri-*
 16 *tory, or political subdivision of a State or territory,*
 17 *under a memorandum of understanding between the*
 18 *Secretary and such State, territory, or political sub-*
 19 *division.*

20 *“(2) PERSONALLY IDENTIFIABLE INFORMA-*
 21 *TION.—Notwithstanding any other provision of law,*
 22 *personally-identifiable information in adverse event*
 23 *reports provided by the Secretary to any health, food,*
 24 *or drug officer or employee of any State, territory, or*

1 *political subdivision of a State or territory, shall*
2 *not—*

3 *“(A) be made publicly available pursuant to*
4 *any State or other law requiring disclosure of*
5 *information or records; or*

6 *“(B) otherwise be disclosed or distributed to*
7 *any party without the written consent of the Sec-*
8 *retary and the person submitting such informa-*
9 *tion to the Secretary.*

10 *“(3) USE OF REPORTS.—Nothing in this section*
11 *shall permit a State, territory, or political subdivi-*
12 *sion of a State or territory, to use any safety report*
13 *received from the Secretary in a manner inconsistent*
14 *with this section.*

15 *“(4) RULE OF CONSTRUCTION.—The submission*
16 *of any report in compliance with this section shall*
17 *not be construed as an admission that the cosmetic*
18 *product involved caused or contributed to the relevant*
19 *adverse event.*

20 **“SEC. 606. GOOD MANUFACTURING PRACTICE.**

21 *“(a) IN GENERAL.—The Secretary shall by regulation*
22 *establish good manufacturing practices for facilities that*
23 *are consistent, to the extent practicable, and appropriate,*
24 *with national and international standards, in accordance*
25 *with section 601. Any such regulations shall be intended*

1 *to protect the public health and ensure that cosmetic prod-*
2 *ucts are not adulterated. Such regulations may allow for*
3 *the Secretary to inspect records necessary to demonstrate*
4 *compliance with good manufacturing practices prescribed*
5 *by the Secretary under this paragraph during an inspection*
6 *conducted under section 704.*

7 “(b) *CONSIDERATIONS.—In establishing regulations*
8 *for good manufacturing practices under this section, the*
9 *Secretary shall take into account the size and scope of the*
10 *businesses engaged in the manufacture of cosmetics, and the*
11 *risks to public health posed by such cosmetics, and provide*
12 *sufficient flexibility to be practicable for all sizes and types*
13 *of facilities to which such regulations will apply. Such regu-*
14 *lations shall include simplified good manufacturing prac-*
15 *tice requirements for smaller businesses, as appropriate, to*
16 *ensure that such regulations do not impose undue economic*
17 *hardship for smaller businesses, and may include longer*
18 *compliance times for smaller businesses. Before issuing reg-*
19 *ulations to implement subsection (a), the Secretary shall*
20 *consult with cosmetics manufacturers, including smaller*
21 *businesses, consumer organizations, and other experts se-*
22 *lected by the Secretary.*

23 “(c) *TIMEFRAME.—The Secretary shall publish a no-*
24 *tice of proposed rulemaking not later than 2 years after*
25 *the date of enactment of the Modernization of Cosmetics*

1 *Regulation Act of 2022 and shall publish a final such rule*
 2 *not later than 3 years after such date of enactment.*

3 **“SEC. 607. REGISTRATION AND PRODUCT LISTING.**

4 “(a) *SUBMISSION OF REGISTRATION.*—

5 “(1) *INITIAL REGISTRATION.*—

6 “(A) *EXISTING FACILITIES.*—*Every person*
 7 *that, on the date of enactment of the Moderniza-*
 8 *tion of Cosmetics Regulation Act of 2022, owns*
 9 *or operates a facility that engages in the manu-*
 10 *facturing or processing of a cosmetic product for*
 11 *distribution in the United States shall register*
 12 *each facility with the Secretary not later than 1*
 13 *year after date of enactment of such Act.*

14 “(B) *NEW FACILITIES.*—*Every person that*
 15 *owns or operates a facility that first engages,*
 16 *after the date of enactment of the Modernization*
 17 *of Cosmetics Regulation Act of 2022, in manu-*
 18 *facturing or processing of a cosmetic product for*
 19 *distribution in the United States, shall register*
 20 *with the Secretary such facility within 60 days*
 21 *of first engaging in such activity or 60 days*
 22 *after the deadline for registration under subpara-*
 23 *graph (A), whichever is later.*

24 “(2) *BIENNIAL RENEWAL OF REGISTRATION.*—*A*
 25 *person required to register a facility under paragraph*

1 (1) shall renew such registrations with the Secretary
2 biennially.

3 “(3) *CONTRACT MANUFACTURERS.*—If a facility
4 manufactures or processes cosmetic products on behalf
5 of a responsible person, the Secretary shall require
6 only a single registration for such facility even if such
7 facility is manufacturing or processing its own cos-
8 metic products or cosmetic products on behalf of more
9 than one responsible person. Such single registration
10 may be submitted to the Secretary by such facility or
11 any responsible person whose products are manufac-
12 tured or processed at such facility.

13 “(4) *UPDATES TO CONTENT.*—A person that is
14 required to register under subsection (a)(1) shall no-
15 tify the Secretary within 60 days of any changes to
16 information required under subsection (b)(2).

17 “(5) *ABBREVIATED RENEWAL REGISTRATIONS.*—
18 The Secretary shall provide for an abbreviated reg-
19 istration renewal process for any person that owns or
20 operates a facility that has not been required to sub-
21 mit updates under paragraph (4) for a registered fa-
22 cility since submission of the most recent registration
23 of such facility under paragraph (1) or (2).

24 “(b) *FORMAT; CONTENTS OF REGISTRATION.*—

1 “(1) *IN GENERAL.*—*Registration information*
2 *under this section may be submitted at such time and*
3 *in such manner as the Secretary may prescribe.*

4 “(2) *CONTENTS.*—*The registration under sub-*
5 *section (a) shall contain—*

6 “(A) *the facility’s name, physical address,*
7 *email address, and telephone number;*

8 “(B) *with respect to any foreign facility, the*
9 *contact for the United States agent of the facil-*
10 *ity, and, if available, the electronic contact infor-*
11 *mation;*

12 “(C) *the facility registration number, if*
13 *any, previously assigned by the Secretary under*
14 *subsection (d);*

15 “(D) *all brand names under which cosmetic*
16 *products manufactured or processed in the facil-*
17 *ity are sold; and*

18 “(E) *the product category or categories and*
19 *responsible person for each cosmetic product*
20 *manufactured or processed at the facility.*

21 “(c) *COSMETIC PRODUCT LISTING.*—

22 “(1) *IN GENERAL.*—*For each cosmetic product,*
23 *the responsible person shall submit to the Secretary a*
24 *cosmetic product listing, or ensure that such submis-*

1 *sion is made, at such time and in such manner as*
2 *the Secretary may prescribe.*

3 “(2) *COSMETIC PRODUCT LISTING.*—*The respon-*
4 *sible person of a cosmetic product that is marketed on*
5 *the date of enactment of the Modernization of Cos-*
6 *metics Regulation Act of 2022 shall submit to the Sec-*
7 *retary a cosmetic product listing not later than 1*
8 *year after the date of enactment of the Modernization*
9 *of Cosmetics Regulation Act of 2022, or for a cosmetic*
10 *product that is first marketed after the date of enact-*
11 *ment of such Act, within 120 days of marketing such*
12 *product in interstate commerce. Thereafter, any up-*
13 *dates to such listing shall be made annually, con-*
14 *sistent with paragraphs (4) and (5).*

15 “(3) *ABBREVIATED RENEWAL.*—*The Secretary*
16 *shall provide for an abbreviated process for the re-*
17 *newal of any cosmetic product listing under this sub-*
18 *section with respect to which there has been no change*
19 *since the responsible person submitted the previous*
20 *listing.*

21 “(4) *CONTENTS OF LISTING.*—

22 “(A) *IN GENERAL.*—*Each such cosmetic*
23 *product listing shall include—*

1 “(i) the facility registration number of
2 each facility where the cosmetic product is
3 manufactured or processed;

4 “(ii) the name and contact number of
5 the responsible person and the name for the
6 cosmetic product, as such name appears on
7 the label;

8 “(iii) the applicable cosmetic category
9 or categories for the cosmetic product;

10 “(iv) a list of ingredients in the cos-
11 metic product, including any fragrances,
12 flavors, or colors, with each ingredient iden-
13 tified by the name, as required under sec-
14 tion 701.3 of title 21, Code of Federal Regu-
15 lations (or any successor regulations), or by
16 the common or usual name of the ingre-
17 dient; and

18 “(v) the product listing number, if any
19 previously assigned by the Secretary under
20 subsection (d).

21 “(B) *FLEXIBLE LISTINGS*.—A single listing
22 submission for a cosmetic product may include
23 multiple cosmetic products with identical formu-
24 lations, or formulations that differ only with re-

1 *spect to colors, fragrances or flavors, or quantity*
2 *of contents.*

3 “(5) *UPDATES TO CONTENT.*—*A responsible per-*
4 *son that is required to submit a cosmetic product list-*
5 *ing shall submit any updates to such cosmetic prod-*
6 *uct listing annually.*

7 “(6) *SUBMISSION.*—*A responsible person may*
8 *submit product listing information as part of a facil-*
9 *ity registration or separately.*

10 “(d) *FACILITY REGISTRATION AND PRODUCT LISTING*
11 *NUMBERS.*—*At the time of the initial registration of any*
12 *facility under subsection (a)(1) or initial listing of any cos-*
13 *metic product under (c)(1), the Secretary shall assign a fa-*
14 *cility registration number to the facility and a product list-*
15 *ing number to each cosmetic product. The Secretary shall*
16 *not make such product listing number publicly available.*

17 “(e) *CONFIDENTIALITY.*—*In response to a request*
18 *under section 552 of title 5, United States Code, informa-*
19 *tion described in subsection (b)(2)(D) or (c)(4)(A)(i) that*
20 *is derived from a registration or listing under this section*
21 *shall be withheld under section 552(b)(3) of title 5, United*
22 *States Code.*

23 “(f) *SUSPENSIONS.*—

24 “(1) *SUSPENSION OF REGISTRATION OF A FACIL-*
25 *ITY.*—*The Secretary may suspend the registration of*

1 *a facility if the Secretary determines that a cosmetic*
2 *product manufactured or processed by a registered fa-*
3 *cility and distributed in the United States has a rea-*
4 *sonable probability of causing serious adverse health*
5 *consequences or death to humans and the Secretary*
6 *has a reasonable belief that other products manufac-*
7 *tured or processed by the facility may be similarly af-*
8 *ected because of a failure that cannot be isolated to*
9 *a product or products, or is sufficiently pervasive to*
10 *raise concerns about other products manufactured in*
11 *the facility.*

12 *“(2) NOTICE OF SUSPENSION.—Before sus-*
13 *pending a facility registration under this section, the*
14 *Secretary shall provide—*

15 *“(A) notice to the facility registrant of the*
16 *cosmetic product or other responsible person, as*
17 *appropriate, of the intent to suspend the facility*
18 *registration, which shall specify the basis of the*
19 *determination by the Secretary that the facility*
20 *registration should be suspended; and*

21 *“(B) an opportunity, within 5 business*
22 *days of the notice provided under subparagraph*
23 *(A), for the responsible person to provide a plan*
24 *for addressing the reasons for possible suspension*
25 *of the facility registration.*

1 “(3) *HEARING ON SUSPENSION.*—*The Secretary*
2 *shall provide the registrant subject to an order under*
3 *paragraph (1) or (2) with an opportunity for an in-*
4 *formal hearing, to be held as soon as possible but not*
5 *later than 5 business days after the issuance of the*
6 *order, or such other time period agreed upon by the*
7 *Secretary and the registrant, on the actions required*
8 *for reinstatement of registration and why the reg-*
9 *istration that is subject to the suspension should be*
10 *reinstated. The Secretary shall reinstate a registra-*
11 *tion if the Secretary determines, based on evidence*
12 *presented, that adequate grounds do not exist to con-*
13 *tinue the suspension of the registration.*

14 “(4) *POST-HEARING CORRECTIVE ACTION*
15 *PLAN.*—*If, after providing opportunity for an infor-*
16 *mal hearing under paragraph (3), the Secretary de-*
17 *termines that the suspension of registration remains*
18 *necessary, the Secretary shall require the registrant to*
19 *submit a corrective action plan to demonstrate how*
20 *the registrant plans to correct the conditions found by*
21 *the Secretary. The Secretary shall review such plan*
22 *not later than 14 business days after the submission*
23 *of the corrective action plan or such other time period*
24 *as determined by the Secretary, in consultation with*
25 *the registrant.*

1 “(5) *VACATING OF ORDER; REINSTATEMENT.*—
 2 *Upon a determination by the Secretary that adequate*
 3 *grounds do not exist to continue the suspension ac-*
 4 *tions, the Secretary shall promptly vacate the suspen-*
 5 *sion and reinstate the registration of the facility.*

6 “(6) *EFFECT OF SUSPENSION.*—*If the registra-*
 7 *tion of the facility is suspended under this section, no*
 8 *person shall introduce or deliver for introduction into*
 9 *commerce in the United States cosmetic products from*
 10 *such facility.*

11 “(7) *NO DELEGATION.*—*The authority conferred*
 12 *by this section to issue an order to suspend a registra-*
 13 *tion or vacate an order of suspension shall not be del-*
 14 *egated to any officer or employee other than the Com-*
 15 *missioner.*

16 **“SEC. 608. SAFETY SUBSTANTIATION.**

17 “(a) *SUBSTANTIATION OF SAFETY.*—*A responsible per-*
 18 *son for a cosmetic product shall ensure, and maintain*
 19 *records supporting, that there is adequate substantiation of*
 20 *safety of such cosmetic product.*

21 “(b) *COAL-TAR HAIR DYE.*—*Subsection (a) shall not*
 22 *apply to coal-tar hair dye that otherwise complies with the*
 23 *requirements of section 601(a). A responsible person for a*
 24 *coal-tar hair dye shall maintain records related to the safe-*
 25 *ty of such product.*

1 “(c) *DEFINITIONS.*—*For purposes of this section:*

2 “(1) *ADEQUATE SUBSTANTIATION OF SAFETY.*—

3 *The term ‘adequate substantiation of safety’ means*
4 *tests or studies, research, analyses, or other evidence*
5 *or information that is considered, among experts*
6 *qualified by scientific training and experience to*
7 *evaluate the safety of cosmetic products and their in-*
8 *redients, sufficient to support a reasonable certainty*
9 *that a cosmetic product is safe.*

10 “(2) *SAFE.*—*The term ‘safe’ means that the cos-*
11 *metic product, including any ingredient thereof, is*
12 *not injurious to users under the conditions of use pre-*
13 *scribed in the labeling thereof, or under such condi-*
14 *tions of use as are customary or usual. The Secretary*
15 *shall not consider a cosmetic ingredient or cosmetic*
16 *product injurious to users solely because it can cause*
17 *minor and transient reactions or minor and transient*
18 *skin irritations in some users. In determining for*
19 *purposes of this section whether a cosmetic product is*
20 *safe, the Secretary may consider, as appropriate and*
21 *available, the cumulative or other relevant exposure to*
22 *the cosmetic product, including any ingredient there-*
23 *of.*

1 **“SEC. 609. LABELING.**

2 “(a) *GENERAL REQUIREMENT.*—*Each cosmetic prod-*
 3 *uct shall bear a label that includes a domestic address, do-*
 4 *mestic phone number, or electronic contact information,*
 5 *which may include a website, through which the responsible*
 6 *person can receive adverse event reports with respect to such*
 7 *cosmetic product.*

8 “(b) *FRAGRANCE ALLERGENS.*—*The responsible person*
 9 *shall identify on the label of a cosmetic product each fra-*
 10 *grance allergen included in such cosmetic product. Sub-*
 11 *stances that are fragrance allergens for purposes of this sub-*
 12 *section shall be determined by the Secretary by regulation.*
 13 *The Secretary shall issue a notice of proposed rulemaking*
 14 *promulgating the regulation implementing this requirement*
 15 *not later than 18 months after the date of enactment of the*
 16 *Modernization of Cosmetics Regulation Act of 2022, and not*
 17 *later than 180 days after the date on which the public com-*
 18 *ment period on the proposed rulemaking closes, shall issue*
 19 *a final rulemaking. In promulgating regulations imple-*
 20 *menting this subsection, the Secretary shall consider inter-*
 21 *national, State, and local requirements for allergen disclo-*
 22 *sure, including the substance and format of requirements*
 23 *in the European Union, and may establish threshold levels*
 24 *of amounts of substances subject to disclosure pursuant to*
 25 *such regulations.*

26 “(c) *COSMETIC PRODUCTS FOR PROFESSIONAL USE.*—

1 “(1) *DEFINITION OF PROFESSIONAL.*—For pur-
 2 poses of this subsection, the term ‘professional’ means
 3 an individual who is licensed by an official State au-
 4 thority to practice in the field of cosmetology, nail
 5 care, barbering, or esthetics.

6 “(2) *PROFESSIONAL USE LABELING.*—A cosmetic
 7 product introduced into interstate commerce and in-
 8 tended to be used only by a professional shall bear a
 9 label that—

10 “(A) contains a clear and prominent state-
 11 ment that the product shall be administered or
 12 used only by licensed professionals; and

13 “(B) is in conformity with the requirements
 14 of the Secretary for cosmetics labeling under this
 15 Act and section 4(a) of the Fair Packaging and
 16 Labeling Act.

17 **“SEC. 610. RECORDS.**

18 “(a) *IN GENERAL.*—If the Secretary has a reasonable
 19 belief that a cosmetic product, including an ingredient in
 20 such cosmetic product, and any other cosmetic product that
 21 the Secretary reasonably believes is likely to be affected in
 22 a similar manner, is likely to be adulterated such that the
 23 use or exposure to such product presents a threat of serious
 24 adverse health consequences or death to humans, each re-
 25 sponsible person and facility shall, at the request of an offi-

1 cer or employee duly designated by the Secretary, permit
2 such officer or employee, upon presentation of appropriate
3 credentials and a written notice to such person, at reason-
4 able times and within reasonable limits and in a reasonable
5 manner, to have access to and copy all records relating to
6 such cosmetic product, and to any other cosmetic product
7 that the Secretary reasonably believes is likely to be affected
8 in a similar manner, that are needed to assist the Secretary
9 in determining whether the cosmetic product is adulterated
10 and presents a threat of serious adverse health consequences
11 or death to humans. This subsection shall not be construed
12 to extend to recipes or formulas for cosmetics, financial
13 data, pricing data, personnel data (other than data as to
14 qualification of technical and professional personnel per-
15 forming functions subject to this Act), research data (other
16 than safety substantiation data for cosmetic products and
17 their ingredients), or sales data (other than shipment data
18 regarding sales).

19 “(b) *RULE OF CONSTRUCTION.*—Nothing in this sec-
20 tion shall be construed to limit the authority of the Sec-
21 retary to inspect records or require establishment and
22 maintenance of records under any other provision of this
23 Act, including section 605 or 606.

1 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

2 “(a) *IN GENERAL.*—If the Secretary determines that
3 there is a reasonable probability that a cosmetic is adulter-
4 ated under section 601 or misbranded under section 602
5 and the use of or exposure to such cosmetic will cause seri-
6 ous adverse health consequences or death, the Secretary shall
7 provide the responsible person with an opportunity to vol-
8 untarily cease distribution and recall such article. If the
9 responsible person refuses to or does not voluntarily cease
10 distribution or recall such cosmetic within the time and
11 manner prescribed by the Secretary (if so prescribed), the
12 Secretary may, by order, require, as the Secretary deter-
13 mines necessary, such person to immediately cease distribu-
14 tion of such article.

15 “(b) *HEARING.*—The Secretary shall provide the re-
16 sponsible person who is subject to an order under subsection
17 (a) with an opportunity for an informal hearing, to be held
18 not later than 10 days after the date of issuance of the order,
19 on whether adequate evidence exists to justify the order.

20 “(c) *ORDER RESOLUTION.*—After an order is issued
21 according to the process under subsections (a) and (b), the
22 Secretary shall, except as provided in subsection (d)—

23 “(1) vacate the order, if the Secretary determines
24 that inadequate grounds exist to support the actions
25 required by the order;

1 “(2) continue the order ceasing distribution of
2 the cosmetic until a date specified in such order; or

3 “(3) amend the order to require a recall of the
4 cosmetic, including any requirements to notify appro-
5 priate persons, a timetable for the recall to occur, and
6 a schedule for updates to be provided to the Secretary
7 regarding such recall.

8 “(d) ACTION FOLLOWING ORDER.—Any person who is
9 subject to an order pursuant to paragraph (2) or (3) of sub-
10 section (c) shall immediately cease distribution of or recall,
11 as applicable, the cosmetic and provide notification as re-
12 quired by such order.

13 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
14 retary determines necessary, the Secretary may require the
15 person subject to an order pursuant to subsection (a) or an
16 amended order pursuant to paragraph (2) or (3) of sub-
17 section (c) to provide either a notice of a recall order for,
18 or an order to cease distribution of, such cosmetic, as appli-
19 cable, under this section to appropriate persons, including
20 persons who manufacture, distribute, import, or offer for
21 sale such product that is the subject of an order and to the
22 public.

23 “(f) PUBLIC NOTIFICATION.—In conducting a recall
24 under this section, the Secretary shall—

1 “(1) ensure that a press release is published re-
2 garding the recall, and that alerts and public notices
3 are issued, as appropriate, in order to provide notifi-
4 cation—

5 “(A) of the recall to consumers and retailers
6 to whom such cosmetic was, or may have been,
7 distributed; and

8 “(B) that includes, at a minimum—

9 “(i) the name of the cosmetic subject to
10 the recall;

11 “(ii) a description of the risk associ-
12 ated with such article; and

13 “(iii) to the extent practicable, infor-
14 mation for consumers about similar cos-
15 metics that are not affected by the recall;
16 and

17 “(2) ensure publication, as appropriate, on the
18 website of the Food and Drug Administration of an
19 image of the cosmetic that is the subject of the press
20 release described in paragraph (1), if available.

21 “(g) NO DELEGATION.—The authority conferred by
22 this section to order a recall or vacate a recall order shall
23 not be delegated to any officer or employee other than the
24 Commissioner.

1 “(h) *EFFECT.*—Nothing in this section shall affect the
 2 *authority of the Secretary to request or participate in a*
 3 *voluntary recall, or to issue an order to cease distribution*
 4 *or to recall under any other provision of this chapter.*

5 **“SEC. 612. SMALL BUSINESSES.**

6 “(a) *IN GENERAL.*—Responsible persons, and owners
 7 *and operators of facilities, whose average gross annual sales*
 8 *in the United States of cosmetic products for the previous*
 9 *3-year period is less than \$1,000,000, adjusted for inflation,*
 10 *and who do not engage in the manufacturing or processing*
 11 *of the cosmetic products described in subsection (b), shall*
 12 *be considered small businesses and not subject to the re-*
 13 *quirements of section 606 or 607.*

14 “(b) *REQUIREMENTS APPLICABLE TO ALL MANUFAC-*
 15 *TURERS AND PROCESSORS OF COSMETICS.*—The exemp-
 16 *tions under subsection (a) shall not apply to any respon-*
 17 *sible person or facility engaged in the manufacturing or*
 18 *processing of any of the following products:*

19 “(1) *Cosmetic products that regularly come into*
 20 *contact with mucus membrane of the eye under condi-*
 21 *tions of use that are customary or usual.*

22 “(2) *Cosmetic products that are injected.*

23 “(3) *Cosmetic products that are intended for in-*
 24 *ternal use.*

1 “(4) *Cosmetic products that are intended to alter*
 2 *appearance for more than 24 hours under conditions*
 3 *of use that are customary or usual and removal by*
 4 *the consumer is not part of such conditions of use*
 5 *that are customary or usual.*

6 **“SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FA-**
 7 **CILITIES.**

8 “(a) *IN GENERAL.*—Notwithstanding any other provi-
 9 *sion of law, except as provided in subsection (b), a cosmetic*
 10 *product or facility that is also subject to the requirements*
 11 *of chapter V shall be exempt from the requirements of sec-*
 12 *tions 605, 606, 607, 608, 609(a), 610, and 611.*

13 “(b) *EXCEPTION.*—A facility described in subsection
 14 *(a) that also manufactures or processes cosmetic products*
 15 *that are not subject to the requirements of chapter V shall*
 16 *not be exempt from the requirements of sections 605, 606,*
 17 *607, 608, 609(a), 610, and 611, with respect to such cos-*
 18 *metic products.*

19 **“SEC. 614. PREEMPTION.**

20 “(a) *IN GENERAL.*—No State or political subdivision
 21 *of a State may establish or continue in effect any law, regu-*
 22 *lation, order, or other requirement for cosmetics that is dif-*
 23 *ferent from or in addition to, or otherwise not identical*
 24 *with, any requirement applicable under this chapter with*
 25 *respect to registration and product listing, good manufac-*

1 turing practice, recordkeeping, recalls, adverse event report-
2 ing, or safety substantiation.

3 “(b) *LIMITATION.*—Nothing in the amendments to this
4 Act made by the Modernization of Cosmetics Regulation Act
5 of 2022 shall be construed to preempt any State statute,
6 public initiative, referendum, regulation, or other State ac-
7 tion, except as expressly provided in subsection (a). Not-
8 withstanding subsection (a), nothing in this section shall
9 be construed to prevent any State from prohibiting the use
10 or limiting the amount of an ingredient in a cosmetic prod-
11 uct, or from continuing in effect a requirement of any State
12 that is in effect at the time of enactment of the Moderniza-
13 tion of Cosmetics Regulation Act of 2022 for the reporting
14 to the State of an ingredient in a cosmetic product.

15 “(c) *SAVINGS.*—Nothing in the amendments to this Act
16 made by the Modernization of Cosmetics Regulation Act of
17 2022, nor any standard, rule, requirement, regulation, or
18 adverse event report shall be construed to modify, preempt,
19 or displace any action for damages or the liability of any
20 person under the law of any State, whether statutory or
21 based in common law.

22 “(d) *RULE OF CONSTRUCTION.*—Nothing in this sec-
23 tion shall be construed to amend, expand, or limit the provi-
24 sions under section 752.”.

1 **SEC. 803. ENFORCEMENT AND CONFORMING AMENDMENTS.**

2 (a) *IN GENERAL.*—

3 (1) *PROHIBITED ACTS.*—Section 301 of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331),
5 as amended by section 506, is further amended—

6 (A) by adding at the end the following:

7 “(ggg) The failure to register or submit listing infor-
8 mation in accordance with section 607.

9 “(hhh) The refusal or failure to follow an order under
10 section 611.”; and

11 (B) in paragraph (d), by striking “or 564”
12 and inserting “, 564, or 607”.

13 (2) *ADULTERATED PRODUCTS.*—Section 601 of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 361) is amended by adding at the end the following:

16 “(f) If it has been manufactured or processed under
17 conditions that do not meet good manufacturing practice
18 regulations, as prescribed by the Food and Drug Adminis-
19 tration in accordance with section 606.

20 “(g) If it is a cosmetic product, and the cosmetic prod-
21 uct, including each ingredient in the cosmetic product, does
22 not have adequate substantiation for safety, as defined in
23 section 608(c).”.

24 (3) *MISBRANDED COSMETICS.*—Section 602(b) of
25 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
26 362(b)) is amended—

1 (A) by striking “and (2)” and inserting
2 “(2)”; and

3 (B) by inserting after “numerical count”
4 the following: “; and (3) the information re-
5 quired under section 609”.

6 (4) *ADVERSE EVENT REPORTING.*—*The Federal*
7 *Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)*
8 *is amended—*

9 (A) in section 301(e) (21 U.S.C. 331(e))—

10 (i) by striking “564, 703” and insert-
11 ing “564, 605, 703”; and

12 (ii) by striking “564, 760” and insert-
13 ing “564, 605, 611, 760”;

14 (B) in section 301(ii) (21 U.S.C. 331(ii))—

15 (i) by striking “760 or 761) or” and
16 inserting “604, 760, or 761) or”; and

17 (ii) by inserting “or required under
18 section 605(a)” after “report (as defined
19 under section 760 or 761”;

20 (C) in section 801(a) (21 U.S.C. 381(a))—

21 (i) by striking “under section 760 or
22 761” and inserting “under section 605, 760,
23 or 761”;

(ii) by striking “defined in such section 760 or 761” and inserting “defined in section 604, 760, or 761”;

(iii) by striking “of such section 760 or 761” and inserting “of such section 605, 760, or 761”; and

(iv) by striking “described in such section 760 or 761” and inserting “described in such section 605, 760, or 761”; and

(D) in section 801(b) (21 U.S.C. 381(b))—

(i) by striking “requirements of sections 760 or 761,” and inserting “requirements of section 605, 760, or 761”;

(ii) by striking “as defined in section 760 or 761” and inserting “as defined in section 604, 760, or 761”; and

(iii) by striking “with section 760 or 761” and inserting “with section 605, 760, or 761”.

(b) *EFFECTIVE DATES.*—

(1) *IN GENERAL.*—The amendments made by subsection (a) shall take effect on the date that is 1 year after the date of enactment of this Act.

(2) *LABELING REQUIREMENT.*—Section 609(a) of the Federal Food, Drug, and Cosmetic Act, as added

1 *by section 802, shall take effect on the date that is 2*
 2 *years after the date of enactment of this Act.*

3 *(c) CONFIDENTIALITY.—*

4 *(1) IN GENERAL.—The Secretary shall take ap-*
 5 *propriate measures to ensure that there are in effect*
 6 *effective procedures to prevent the unauthorized dis-*
 7 *closure of any trade secret or confidential commercial*
 8 *information that is obtained by the Secretary of*
 9 *Health and Human Services pursuant to this subtitle,*
 10 *including the amendments made by this subtitle.*

11 *(2) CLARIFICATION.—Nothing in this subtitle,*
 12 *including the amendments made by this subtitle, shall*
 13 *be construed to authorize the disclosure of information*
 14 *that is prohibited from disclosure under section 301(j)*
 15 *of the Federal Food, Drug, and Cosmetic Act (21*
 16 *U.S.C. 331(j)) or section 1905 of title 18, United*
 17 *States Code, or that is subject to withholding under*
 18 *section 552(b)(4) of title 5, United States Code.*

19 **SEC. 804. RECORDS INSPECTION.**

20 *Section 704(a)(1) of the Federal Food, Drug, and Cos-*
 21 *metic Act (21 U.S.C. 374(a)(1)) is amended by inserting*
 22 *after the second sentence the following: “In the case of a*
 23 *facility (as defined in section 604) that manufactures or*
 24 *processes cosmetic products, the inspection shall extend to*
 25 *all records and other information described in sections 605,*

1 606, and 610, when the standard for records inspection
2 under such section applies.”.

3 **SEC. 805. TALC-CONTAINING COSMETICS.**

4 *The Secretary of Health and Human Services—*

5 *(1) not later than one year after the date of en-*
6 *actment of this Act, shall promulgate proposed regula-*
7 *tions to establish and require standardized testing*
8 *methods for detecting and identifying asbestos in talc-*
9 *containing cosmetic products; and*

10 *(2) not later than 180 days after the date on*
11 *which the public comment period on the proposed reg-*
12 *ulations closes, shall issue such final regulations.*

13 **SEC. 806. PFAS IN COSMETICS.**

14 *(a) IN GENERAL.—The Secretary of Health and*
15 *Human Services (referred to in this section as the “Sec-*
16 *retary”)* shall assess the use of perfluoroalkyl and
17 polyfluoroalkyl substances in cosmetic products and the sci-
18 entific evidence regarding the safety of such use in cosmetic
19 products, including any risks associated with such use. In
20 conducting such assessment, the Secretary may, as appro-
21 priate, consult with the National Center for Toxicological
22 Research.

23 *(b) REPORT.—Not later than 3 years after enactment*
24 *of this Act, the Secretary shall publish on the website of*

1 *the Food and Drug Administration a report summarizing*
 2 *the results of the assessment conducted under subsection (a).*

3 **SEC. 807. SENSE OF THE SENATE ON ANIMAL TESTING.**

4 *It is the sense of the Senate that animal testing should*
 5 *not be used for the purposes of safety testing on cosmetic*
 6 *products and should be phased out with the exception of*
 7 *appropriate allowances.*

8 **SEC. 808. FUNDING.**

9 *There is authorized to be appropriated \$14,200,000 for*
 10 *fiscal year 2023, \$25,960,000 for fiscal year 2024, and*
 11 *\$41,890,000 for each of fiscal years 2025 through 2027, for*
 12 *purposes of conducting the activities under this subtitle (in-*
 13 *cluding the amendments made by this subtitle) and hiring*
 14 *personnel required to carry out this subtitle (including the*
 15 *amendments made by this subtitle).*

16 ***Subtitle B—Dietary Supplements***

17 **SEC. 811. REGULATION OF DIETARY SUPPLEMENTS.**

18 *(a) IN GENERAL.—Chapter IV of the Federal Food,*
 19 *Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended*
 20 *by adding after section 403C of such Act (21 U.S.C. 343–*
 21 *3) the following:*

22 **“SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIREMENT.**

23 *“(a) IN GENERAL.—Beginning on the date specified*
 24 *in subsection (b)(4), each dietary supplement marketed in*
 25 *the United States shall be listed with the Secretary in ac-*

1 *cordance with this section. Each such listing shall include,*
2 *with respect to the dietary supplement, the information*
3 *specified in subsection (b)(1).*

4 “(b) *REQUIREMENTS.*—

5 “(1) *IN GENERAL.*—*The manufacturer, packer,*
6 *or distributor of a dietary supplement whose name*
7 *(pursuant to section 403(e)(1)) appears on the label*
8 *of a dietary supplement marketed in the United*
9 *States (referred to in this section as the ‘responsible*
10 *person’), or if the responsible person is a foreign enti-*
11 *ty, the United States agent of such person, shall sub-*
12 *mit to the Secretary in accordance with this section*
13 *the following information for a dietary supplement*
14 *that is marketed:*

15 “(A) *Any name of the dietary supplement*
16 *and the statement of identity, including brand*
17 *name and specified flavors, if applicable.*

18 “(B) *The name and address of the respon-*
19 *sible person and the name and email address of*
20 *the owner, operator, or agent in charge of the re-*
21 *sponsible person.*

22 “(C) *The name, domestic address, and*
23 *email address for the United States agent, if the*
24 *responsible person is a foreign entity.*

1 “(D) *The business name and full address of*
2 *all locations at which the responsible person*
3 *manufactures, packages, labels, or holds the die-*
4 *tary supplement.*

5 “(E) *A list of all ingredients in each such*
6 *dietary supplement required under sections 101.4*
7 *and 101.36, title 21, Code of Federal Regulations*
8 *(or any successor regulations) to appear on the*
9 *label of a dietary supplement, including—*

10 “(i) *where applicable, ingredients in a*
11 *proprietary blend as described in section*
12 *101.36(c) of title 21, Code of Federal Regu-*
13 *lations (or any successor regulations);*

14 “(ii) *the amount per serving of each*
15 *listed dietary ingredient;*

16 “(iii) *if required by section 101.36 of*
17 *title 21, Code of Federal Regulations (or*
18 *any successor regulations), the percent of*
19 *the daily value of each listed dietary ingre-*
20 *dient; and*

21 “(iv) *the amount per serving of dietary*
22 *ingredients within a proprietary blend.*

23 “(F) *The number of servings per container*
24 *for each container size.*

25 “(G) *The directions for use.*

1 “(H) Warnings, notice, and safe handling
2 statements, as required by section 101.17 of title
3 21, Code of Federal Regulations (or any suc-
4 cessor regulations).

5 “(I) Allergen statements for major food al-
6 lergens (pursuant to sections 403(w) and
7 403(x)).

8 “(J) The form of the dietary supplement
9 (such as tablets, capsules, powders, liquids,
10 softgels, and gummies).

11 “(K) Any health claims or structure or
12 function claims.

13 “(L) The dietary supplement product listing
14 number for the dietary supplement provided by
15 the Secretary in accordance with subsection (c).

16 “(2) *FORMAT*.—The Secretary may require that
17 a listing submitted under paragraph (1) be submitted
18 in an electronic format. Upon receipt of a complete
19 listing under paragraph (1), the Secretary shall
20 promptly notify the responsible person of the receipt
21 of such listing.

22 “(3) *LISTING CONTENT*.—A single listing sub-
23 mission for a dietary supplement under paragraph
24 (1) may include multiple dietary supplements with
25 identical formulations and forms, or formulations of

1 *the same form, that differ only with respect to color,*
 2 *excipients, or flavorings, whether offered in a single*
 3 *package size or in multiple package sizes.*

4 “(4) *TIMING.*—

5 “(A) *IN GENERAL.*—

6 “(i) *DIETARY SUPPLEMENTS ON THE*
 7 *MARKET.*—*In the case of a dietary supple-*
 8 *ment that is being offered in interstate com-*
 9 *merce on or before January 1, 2024, a list-*
 10 *ing for each such dietary supplement intro-*
 11 *duced or delivered for introduction into*
 12 *interstate commerce shall be submitted by*
 13 *the responsible person to the Secretary*
 14 *under this subsection not later than 18*
 15 *months after the date of enactment of the*
 16 *Food and Drug Administration Safety and*
 17 *Landmark Advancements Act of 2022.*

18 “(ii) *NEW DIETARY SUPPLEMENTS.*—

19 *In the case of a dietary supplement that is*
 20 *not being offered in interstate commerce on*
 21 *or before January 1, 2024, a listing for each*
 22 *such dietary supplement introduced or de-*
 23 *livered for introduction into interstate com-*
 24 *merce that has not been included in any*
 25 *listing previously submitted by the respon-*

1 sible person to the Secretary under this sub-
2 section shall be submitted to the Secretary
3 at the time of introduction into interstate
4 commerce.

5 “(B) *DISCONTINUED DIETARY SUPPLE-*
6 *MENTS.—The responsible person shall notify the*
7 *Secretary within one year of the date of dis-*
8 *continuance of a dietary supplement required to*
9 *be listed with the Secretary under paragraph (1)*
10 *for which the responsible person has discontinued*
11 *commercial marketing.*

12 “(C) *CHANGES TO EXISTING LISTINGS.—*
13 *The responsible person shall submit to the Sec-*
14 *retary a change or modification to listing infor-*
15 *mation submitted under paragraph (1) included*
16 *on the label for a dietary supplement at the time*
17 *the dietary supplement with the change or modi-*
18 *fication is introduced into interstate commerce.*

19 “(5) *ADDITIONAL INFORMATION.—The respon-*
20 *sible person shall provide upon request from the Sec-*
21 *retary, within 10 calendar days of such request, the*
22 *full business name and physical and mailing address*
23 *from which the responsible person receives a dietary*
24 *ingredient or combination of dietary ingredients that*
25 *the responsible person uses in the manufacture of the*

1 *dietary supplement or, if applicable, from which the*
 2 *responsible person receives the dietary supplement.*

3 “(c) *PRODUCT LISTING NUMBER AND DIETARY SUP-*
 4 *PLEMENT ELECTRONIC DATABASE.*—

5 “(1) *DIETARY SUPPLEMENT PRODUCT LISTING*
 6 *NUMBER.*—*The Secretary shall provide each dietary*
 7 *supplement listed in accordance with subsection (b)(1)*
 8 *a dietary supplement product listing number, which*
 9 *may apply to multiple dietary supplements with*
 10 *identical formulations, or formulations that differ*
 11 *only with respect to color, excipients, or flavorings,*
 12 *including dietary supplements offered in a single*
 13 *package size or in multiple package sizes. The Sec-*
 14 *retary shall provide a process for a responsible person*
 15 *to reserve dietary supplement listing numbers in ad-*
 16 *vance of listing under subsection (b)(1).*

17 “(2) *ELECTRONIC DATABASE.*—*Not later than 2*
 18 *years after the date of enactment of the Food and*
 19 *Drug Administration Safety and Landmark Advance-*
 20 *ments Act of 2022, the Secretary shall establish and*
 21 *maintain an electronic database that is publicly*
 22 *available and contains information submitted under*
 23 *subsection (b)(1) (except for the information sub-*
 24 *mitted under subparagraphs (D) and (E)(iv) of such*
 25 *subsection). The Secretary shall make such informa-*

1 *tion maintained in the electronic database publicly*
 2 *searchable, including by dietary supplement product*
 3 *listing number, and by any field of information or*
 4 *combination of fields of information provided under*
 5 *subsection (b)(1).*

6 “(3) *CONFIDENTIAL INFORMATION.*—*In response*
 7 *to a request under section 552 of title 5, United*
 8 *States Code, information described in subparagraph*
 9 *(D) or (E)(iv) of subsection (b)(1) that is derived*
 10 *from a listing under this section shall be withheld*
 11 *under section 552(b)(3) of title 5, United States Code.*

12 “(d) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*
 13 *tion shall be construed—*

14 “(1) *to limit the authority of the Secretary to in-*
 15 *spect or copy records or to require the establishment*
 16 *and maintenance of records under any other provi-*
 17 *sion of this Act;*

18 “(2) *to authorize the disclosure of information*
 19 *that is prohibited from disclosure under section 301(j)*
 20 *of this Act or section 1905 of title 18, United States*
 21 *Code, or that is subject to withholding under section*
 22 *552(b)(4) of title 5, United States Code; or*

23 “(3) *to grant the Secretary authority to require*
 24 *the approval of a dietary supplement prior to mar-*
 25 *keting.*

1 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
 2 *authorized to be appropriated \$7,498,080 for fiscal year*
 3 *2023, and \$6,300,000 for each of fiscal years 2024 through*
 4 *2027, for purposes of conducting the activities under this*
 5 *section and hiring personnel required to carry out this sec-*
 6 *tion.*”.

7 (b) *GUIDANCE.*—*Not later than 18 months after the*
 8 *date of enactment of this Act, the Secretary of Health and*
 9 *Human Services shall publish final guidance related to the*
 10 *draft guidance titled, “Dietary Supplements: New Dietary*
 11 *Ingredient Notifications and Related Issues; Revised Draft*
 12 *Guidance for Industry”, issued August 12, 2016, consistent*
 13 *with section 403D of the Federal Food, Drug, and Cosmetic*
 14 *Act, as added by subsection (a).*

15 (c) *INSPECTIONS FOR CERTAIN DIETARY SUPPLE-*
 16 *MENTS.*—*The Secretary of Health and Human Services*
 17 *shall direct resources to inspections of facilities, suppliers,*
 18 *and dietary supplement types that present a high risk to*
 19 *public health (as identified by the Secretary).*

20 (d) *MISBRANDING.*—*Section 403 of the Federal Food,*
 21 *Drug, and Cosmetic Act (21 U.S.C. 343) is amended by*
 22 *adding at the end the following:*

23 “(z) *If it is a dietary supplement for which a respon-*
 24 *sible person or the United States agent of such a person*
 25 *is required under section 403D to file a listing, file a change*

1 *to an existing listing, or provide additional information to*
 2 *the Secretary, and such person or agent has failed to comply*
 3 *with any such requirements under section 403D with re-*
 4 *spect to such dietary supplement.”.*

5 *(e) NEW PROHIBITED ACT.—Section 301 of the Fed-*
 6 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 331), as*
 7 *amended by section 803(a), is further amended by adding*
 8 *at the end the following:*

9 *“(iii) The introduction or delivery for introduction*
 10 *into interstate commerce of any product marketed as a die-*
 11 *tary supplement that does not meet the definition of a die-*
 12 *tary supplement under section 201(ff).*

13 *“(jjj) The introduction or delivery for introduction*
 14 *into interstate commerce of a dietary supplement that has*
 15 *been prepared, packed, or held using the assistance of, or*
 16 *at the direction of, a person debarred under section 306.”.*

17 ***Subtitle C—In Vitro Clinical Tests***

18 ***SEC. 821. SHORT TITLE.***

19 *(a) SHORT TITLE.—This subtitle may be cited as the*
 20 *“Verifying Accurate Leading-edge IVCT Development Act*
 21 *of 2022” or the “VALID Act of 2022”.*

22 ***SEC. 822. DEFINITIONS.***

23 *(a) IN GENERAL.—Section 201 of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 321) is amended—*

25 *(1) by adding at the end the following:*

1 “(ss)(1) *The term ‘in vitro clinical test’ means an arti-*
 2 *cle specified in subparagraph (2) that is intended to be used*
 3 *in the collection, preparation, analysis, or in vitro clinical*
 4 *examination of specimens taken or derived from the human*
 5 *body for the purpose of—*

6 “(A) *identifying or diagnosing a disease or con-*
 7 *dition;*

8 “(B) *providing information for diagnosing,*
 9 *screening, measuring, detecting, predicting,*
 10 *prognosing, analyzing, or monitoring a disease or*
 11 *condition, including by making a determination of an*
 12 *individual’s state of health; or*

13 “(C) *selecting, monitoring, or informing therapy*
 14 *or treatment for a disease or condition.*

15 “(2) *An article specified in this subparagraph is—*

16 “(A) *a test kit;*

17 “(B) *a test system;*

18 “(C) *a test protocol or laboratory test protocol;*

19 “(D) *an instrument (as defined in section*
 20 *587(11));*

21 “(E) *a specimen receptacle (as defined in section*
 22 *587(16));*

23 “(F) *software, excluding software that is ex-*
 24 *cluded by section 520(o) from the definition of a de-*
 25 *vice under section 201(h), that—*

1 “(i) is a component or part of another in
2 *vitro* clinical test or analyzes, processes, or inter-
3 prets a signal or pattern from another in *vitro*
4 clinical test; and

5 “(ii) does not analyze, process, or interpret
6 a signal, pattern, or medical image from a de-
7 vice; and

8 “(G) subject to subparagraph (3), a component
9 or part of a test, a test protocol, an instrument, an
10 article, or software described in any of clauses (A)
11 through (D) of such subparagraph, whether alone or
12 in combination, including reagents, calibrators, and
13 controls.

14 “(3) Notwithstanding subparagraph (2)(G), an article
15 intended to be used as a component or part of an *in vitro*
16 clinical test described in subparagraph (1) is excluded from
17 the definition in subparagraph (1) if the article consists
18 of any of the following:

19 “(A) Blood, blood components, or human cells or
20 tissues, from the time of acquisition, donation, or re-
21 covery of such article, including determination of
22 donor eligibility, as applicable, until such time as the
23 article is released as a component or part of an *in*
24 *vitro* clinical test by the establishment that collected
25 such article.

1 “(B) *An article used for invasive sampling, a*
 2 *needle, or a lancet, except to the extent such article,*
 3 *needle, or lancet is an integral component of an arti-*
 4 *cle for holding, storing, or transporting a specimen.*

5 “(C) *General purpose laboratory equipment.*”;

6 (2) *by adding at the end of section 201(g) the*
 7 *following:*

8 “(3) *The term ‘drug’ does not include an in vitro clin-*
 9 *ical test.*”; and

10 (3) *in section 201(h)(1), in the matter following*
 11 *clause (C), by striking “section 520(o)” and inserting*
 12 *“section 520(o) or an in vitro clinical test”.*

13 (b) *EXCLUSION FROM DEFINITION OF BIOLOGICAL*
 14 *PRODUCT.—Section 351(i)(1) of the Public Health Service*
 15 *Act (42 U.S.C. 262(i)(1)) is amended—*

16 (1) *by striking “(1) The term ‘biological product’*
 17 *means” and inserting “(1)(A) The term ‘biological*
 18 *product’ means”; and*

19 (2) *by adding at the end the following:*

20 “(B) *The term ‘biological product’ does not in-*
 21 *clude an in vitro clinical test as defined in section*
 22 *201(ss) of the Federal Food, Drug, and Cosmetic*
 23 *Act.*”.

24 (c) *IN VITRO CLINICAL TEST DEFINITION.—In this*
 25 *subtitle, the term “in vitro clinical test” has the meaning*

1 *given such term in section 201(ss) of the Federal Food,*
 2 *Drug, and Cosmetic Act, as added by subsection (a).*

3 **SEC. 823. REGULATION OF IN VITRO CLINICAL TESTS.**

4 *The Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 5 *301 et seq.) is amended—*

6 *(1) by amending the heading of chapter V to*
 7 *read as follows: “**DRUGS, DEVICES, AND IN***
 8 ***VITRO CLINICAL TESTS**”; and*

9 *(2) by adding at the end of chapter V the fol-*
 10 *lowing:*

11 **“Subchapter J—In Vitro Clinical Tests**

12 **“SEC. 587. DEFINITIONS.**

13 *“In this subchapter:*

14 *“(1) ANALYTICAL VALIDITY.—The term ‘analyt-*
 15 *ical validity’ means, with respect to an in vitro clin-*
 16 *ical test, the ability of the in vitro clinical test, to*
 17 *identify, measure, detect, calculate, or analyze (or as-*
 18 *sist in such identification, measurement, detection,*
 19 *calculation, or analysis of) one or more analytes, bio-*
 20 *markers, substances, or other targets intended to be*
 21 *identified, measured, detected, calculated, or analyzed*
 22 *by the test.*

23 *“(2) APPLICABLE STANDARD.—The term ‘appli-*
 24 *cable standard’, with respect to an in vitro clinical*
 25 *test, means a reasonable assurance of analytical and*

1 *clinical validity for its indications for use, and a rea-*
 2 *sonable assurance of safety for individuals who come*
 3 *into contact with such in vitro clinical test, except*
 4 *that such term, with respect to specimen receptacles*
 5 *and test instruments, means a reasonable assurance of*
 6 *analytical validity for its indications for use and*
 7 *safety for individuals who come into contact with*
 8 *such specimen receptacle or test instrument.*

9 “(3) *CLINICAL USE.*—The term ‘clinical use’
 10 *means the operation, application, or functioning of*
 11 *an in vitro clinical test for the purpose for which it*
 12 *is intended as described in section 201(ss)(1).*

13 “(4) *CLINICAL VALIDITY.*—The term ‘clinical va-
 14 *lidity’ means the ability of an in vitro clinical test*
 15 *to achieve the purpose for which it is intended as de-*
 16 *scribed in section 201(ss)(1).*

17 “(5) *COMPONENT OR PART.*—The term ‘compo-
 18 *nent or part’ means a substance, piece, part, raw ma-*
 19 *terial, software, firmware, labeling, or assembly, in-*
 20 *cluding reagents, that is intended to be included as*
 21 *an aspect of an in vitro clinical test described in sec-*
 22 *tion 201(ss)(1).*

23 “(6) *DEVELOP.*—The term ‘develop’, with respect
 24 *to an in vitro clinical test, means—*

1 “(A) *designing, validating, producing, man-*
2 *ufacturing, remanufacturing, labeling, adver-*
3 *tising, propagating, importing, or assembling an*
4 *in vitro clinical test;*

5 “(B) *modifying an in vitro clinical test, in-*
6 *cluding modifying the indications for use of the*
7 *in vitro clinical test, or modifying an article to*
8 *be an in vitro clinical test; or*

9 “(C) *establishing a test system as described*
10 *or included in a test protocol developed by an-*
11 *other entity unless such test protocol is listed as*
12 *an in vitro clinical test in the comprehensive test*
13 *information system established under section*
14 *587T by that other entity.*

15 “(7) *DEVELOPER.*—*The term ‘developer’ means a*
16 *person who engages in development as described in*
17 *paragraph (6), except the term does not include a lab-*
18 *oratory that—*

19 “(A) *is certified by the Secretary under sec-*
20 *tion 353 of the Public Health Service Act; and*

21 “(B) *assembles for use solely within that*
22 *laboratory, without otherwise developing, an in*
23 *vitro clinical test appropriately listed in the*
24 *comprehensive test information system estab-*
25 *lished under section 587T by a different person.*

1 “(8) *FIRST-OF-A-KIND.*—The term ‘first-of-a-
 2 kind’, with respect to an *in vitro* clinical test, means
 3 that such test has any novel combination of the ele-
 4 ments specified in paragraph (10) that differs from *in*
 5 *vitro* clinical tests that already are legally available
 6 in the United States, except for such tests offered
 7 under section 587C(a)(3), 587C(a)(4), or 587G.

8 “(9) *HIGH-RISK.*—The term ‘high-risk’, with re-
 9 spect to an *in vitro* clinical test or category of *in*
 10 *vitro* clinical tests, means that an undetected inac-
 11 curate result from such test, or such category of tests,
 12 when used as intended—

13 “(A)(i) has the substantial likelihood to re-
 14 sult in serious or irreversible harm or death to
 15 a patient or patients, or would otherwise cause
 16 serious harm to the public health; or

17 “(ii) is reasonably likely to result in the ab-
 18 sence, significant delay, or discontinuation of
 19 life-supporting or life-sustaining medical treat-
 20 ment; and

21 “(B) sufficient mitigating measures are not
 22 able to be established and applied to prevent,
 23 mitigate, or detect the inaccurate result, or other-
 24 wise mitigate the risk resulting from an unde-
 25 tected inaccurate result described in subpara-

1 *graph (A), such that the test would be moderate-*
 2 *risk or low-risk.*

3 “(10) *INDICATIONS FOR USE.*—*The term ‘indica-*
 4 *tions for use’, with respect to an in vitro clinical test,*
 5 *means the following elements:*

6 “(A) *Substance or substances measured by*
 7 *the in vitro clinical test, such as an analyte, pro-*
 8 *tein, or pathogen.*

9 “(B) *Test method.*

10 “(C) *Test purpose or purposes, as described*
 11 *in section 201(ss)(1).*

12 “(D) *Diseases or conditions for which the in*
 13 *vitro clinical test is intended for use, including*
 14 *intended patient populations.*

15 “(E) *Context of use, such as in a clinical*
 16 *laboratory, in a health care facility, prescription*
 17 *home use, over-the-counter use, or direct-to-con-*
 18 *sumer testing.*

19 “(11) *INSTRUMENT.*—

20 “(A) *IN GENERAL.*—*The term ‘instrument’*
 21 *means an analytical or pre-analytical instru-*
 22 *ment.*

23 “(B) *ANALYTIC INSTRUMENT.*—*The term*
 24 *‘analytic instrument’ means an in vitro clinical*
 25 *test that is hardware intended by the hardware*

1 *developer to be used with one or more other in*
 2 *vitro clinical tests to generate a clinical test re-*
 3 *sult, including software used to effectuate the*
 4 *functionality of the hardware.*

5 “(C) *PRE-ANALYTICAL INSTRUMENT.*—*The*
 6 *term ‘pre-analytical instrument’ means an in*
 7 *vitro clinical test that is hardware intended by*
 8 *the hardware developer solely to generate an out-*
 9 *put for use exclusively with one or more analyt-*
 10 *ical instruments as defined in subparagraph (B)*
 11 *and which does not itself generate a clinical test*
 12 *result. Such term may include software used to*
 13 *effectuate the hardware’s functionality.*

14 “(12) *INSTRUMENT FAMILY.*—*The term ‘instru-*
 15 *ment family’ means more than one instrument devel-*
 16 *oped by the same developer for which the developer*
 17 *demonstrates and documents, with respect to all such*
 18 *instruments, that all—*

19 “(A) *have the same basic architecture, de-*
 20 *sign, and performance characteristics;*

21 “(B) *have the same indications for use and*
 22 *capabilities;*

23 “(C) *share the same measurement prin-*
 24 *ciples, detection methods, and reaction condi-*
 25 *tions, as applicable; and*

1 “(D) produce the same or similar analytical
2 results from samples of the same specimen type
3 or types.

4 “(13) *LABORATORY OPERATIONS.*—The term
5 ‘laboratory operations’—

6 “(A) means the conduct of a laboratory ex-
7 amination or other laboratory procedure on ma-
8 terials derived from the human body, including
9 the conduct of an *in vitro* clinical test and asso-
10 ciated activities within or under the oversight of
11 a laboratory and not related to the design of an
12 *in vitro* clinical test; and

13 “(B) includes—

14 “(i) performing pre-analytical and
15 post-analytical processes for an *in vitro*
16 clinical test;

17 “(ii) standard operating procedures
18 and the conduct thereof; and

19 “(iii) preparing reagents or other test
20 materials that do not meet the definition of
21 an *in vitro* clinical test for clinical use
22 under section 201(ss).

23 “(14) *LOW-RISK.*—The term ‘low-risk’, with re-
24 spect to an *in vitro* clinical test or category of *in*
25 *vitro* clinical tests, means that an undetected inac-

1 *curate result from such in vitro clinical test, or such*
 2 *category of in vitro clinical tests, when used as in-*
 3 *tended—*

4 *“(A) would cause only minimal or imme-*
 5 *diately reversible harm, and would lead to only*
 6 *a remote risk of adverse patient impact or ad-*
 7 *verse public health impact; or*

8 *“(B) sufficient mitigating measures are able*
 9 *to be established and applied such that the in*
 10 *vitro clinical test meets the standard described in*
 11 *subparagraph (A).*

12 *“(15) MITIGATING MEASURES.—The term ‘miti-*
 13 *gating measures’—*

14 *“(A) means controls, standards, and other*
 15 *requirements that the Secretary determines,*
 16 *based on evidence, are necessary—*

17 *“(i) for an in vitro clinical test, or a*
 18 *category of in vitro clinical tests, to meet*
 19 *the applicable standard; or*

20 *“(ii) to mitigate the risk of harm ensu-*
 21 *ing from an undetected inaccurate result or*
 22 *misinterpretation of a result; and*

23 *“(B) may include, as required by the Sec-*
 24 *retary, as appropriate, applicable requirements*
 25 *regarding labeling, conformance to performance*

standards and consensus standards, performance testing, submission of clinical data, advertising, website posting of information, clinical studies, postmarket surveillance, user comprehension studies, training, and confirmatory laboratory, clinical findings, the role of a health professional in the testing process, or testing.

“(16) *MODERATE-RISK*.—The term ‘moderate-risk’, with respect to an *in vitro* clinical test or category of *in vitro* clinical tests, means a test or category of tests—

“(A) that, when used as intended, meets the criteria specified in paragraph (9)(A) for classification as high-risk, but one or more mitigating measures are able to be established and applied to prevent or detect an inaccurate result or otherwise sufficiently mitigate such risk, but are not sufficient such that the test is low-risk under the criteria in paragraph (13); or

“(B) for which, when used as intended—

“(i) an undetected inaccurate result would cause only non-life-threatening harm, harm that is medically reversible, or the absence, significant delay, or discontinuation

1 *of necessary treatment that is not life-sup-*
 2 *porting or life-sustaining; and*

3 “(ii) *mitigating measures are not able*
 4 *to be established and applied to prevent or*
 5 *detect such inaccurate result or otherwise*
 6 *sufficiently mitigate the risk of such inac-*
 7 *curate result such that the test would be*
 8 *low-risk under the criteria in paragraph*
 9 *(13).*

10 “(17) *SPECIMEN RECEPTACLE.*—*The term ‘speci-*
 11 *men receptacle’ means an in vitro clinical test in-*
 12 *tended for taking, collecting, holding, storing, or*
 13 *transporting of specimens derived from the human*
 14 *body or for in vitro examination for purposes de-*
 15 *scribed in subparagraph (A) or (B) of section*
 16 *201(ss)(1).*

17 “(18) *TECHNOLOGY.*—*The term ‘technology’—*

18 “(A) *means a set of control mechanisms, en-*
 19 *ergy sources, or operating principles—*

20 “(i) *that do not differ significantly*
 21 *among multiple in vitro clinical tests; and*

22 “(ii) *for which design and development*
 23 *(including analytical and clinical valida-*
 24 *tion, as applicable) of the tests would be ad-*

1 *dressed in a similar manner or through*
 2 *similar procedures; and*

3 “(B) may include clot detection, colori-
 4 *metric (non-immunoassay), electrochemical (non-*
 5 *immunoassay), enzymatic (non-immunoassay),*
 6 *flow cytometry, fluorometry (non-immunoassay),*
 7 *immunoassay, mass spectrometry or chroma-*
 8 *tography, microbial culture, next generation se-*
 9 *quencing, nephelometric or turbidimetric (non-*
 10 *immunoassay), singleplex or multiplex non-NGS*
 11 *nucleic acid analysis, slide-based technology,*
 12 *spectroscopy, and any other technology, as the*
 13 *Secretary determines appropriate.*

14 “(19) *TEST*.—The term ‘test’, unless otherwise
 15 *provided, means an in vitro clinical test.*

16 “(20) *VALID SCIENTIFIC EVIDENCE*.—The term
 17 *‘valid scientific evidence’—*

18 “(A) means, with respect to an in vitro
 19 *clinical test, evidence that—*

20 “(i) has been generated and evaluated
 21 *by persons qualified by training or experi-*
 22 *ence to do so, using procedures generally ac-*
 23 *cepted by other persons so qualified; and*

24 “(ii) forms an appropriate basis for
 25 *concluding by qualified experts whether the*

1 *applicable standard has been met by the in*
2 *vitro clinical test; and*

3 *“(B) may include evidence described in sub-*
4 *paragraph (A) consisting of—*

5 *“(i) peer-reviewed literature;*

6 *“(ii) clinical guidelines;*

7 *“(iii) reports of significant human ex-*
8 *perience with an in vitro clinical test;*

9 *“(iv) bench studies;*

10 *“(v) case studies or histories;*

11 *“(vi) clinical data;*

12 *“(vii) consensus standards;*

13 *“(viii) reference standards;*

14 *“(ix) data registries;*

15 *“(x) postmarket data;*

16 *“(xi) real world data;*

17 *“(xii) clinical trials; and*

18 *“(xiii) data collected in countries other*
19 *than the United States if such data are*
20 *demonstrated to be appropriate for the pur-*
21 *pose of making a regulatory determination*
22 *under this subchapter.*

1 **“SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.**

2 “(a) *IN GENERAL.*—No person shall introduce or de-
3 liver for introduction into interstate commerce any in vitro
4 clinical test, unless—

5 “(1) *an approval of an application filed pursu-*
6 *ant to subsection (a) or (b) of section 587B is effective*
7 *with respect to such in vitro clinical test;*

8 “(2) *the in vitro clinical test is offered under a*
9 *technology certification order in effect under section*
10 *587D(b)(1); or*

11 “(3) *the test is exempt under sections 587C or*
12 *587G from the requirements of section 587B.*

13 “(b) *TRANSFER OR SALE OF IN VITRO CLINICAL*
14 *TESTS.*—

15 “(1) *TRANSFER AND ASSUMPTION OF REGU-*
16 *LATORY OBLIGATIONS.*—If ownership of an in vitro
17 clinical test is sold or transferred in such manner
18 that the developer transfers the regulatory submissions
19 and obligations applicable under this subchapter with
20 respect to the test, the transferee or purchaser becomes
21 the developer of the test and shall have all regulatory
22 obligations applicable to such a test under this sub-
23 chapter. The transferee or purchaser shall update the
24 registration and listing information under section
25 587J for the in vitro clinical test.

1 “(2) *TRANSFER OR SALE OF PREMARKET AP-*
2 *PROVAL.*—

3 “(A) *NOTICE REQUIRED.*—*If a developer of*
4 *an in vitro clinical test transfers or sells the ap-*
5 *proval of the in vitro clinical test, the transferor*
6 *or seller shall—*

7 “(i) *submit a notice of the transfer or*
8 *sale to the Secretary and update the reg-*
9 *istration and listing information under sec-*
10 *tion 587J for the in vitro clinical test; and*

11 “(ii) *submit a supplement to an appli-*
12 *cation if required under section 587B(h).*

13 “(B) *EFFECTIVE DATE OF APPROVAL*
14 *TRANSFER.*—*A transfer or sale described in sub-*
15 *paragraph (A) shall become effective upon com-*
16 *pletion of a transfer or sale described in para-*
17 *graph (1) or the approval of a supplement to an*
18 *application under section 587B(h) if required,*
19 *whichever is later. The transferee or purchaser*
20 *shall update the registration and listing infor-*
21 *mation under section 587J for the in vitro clin-*
22 *ical test within 15 calendar days of the effective*
23 *date of the transfer or sale.*

24 “(3) *TRANSFER OR SALE OF TECHNOLOGY CER-*
25 *TIFICATION.*—

1 “(A) *REQUIREMENTS FOR TRANSFER OR*
 2 *SALE OF TECHNOLOGY CERTIFICATION.*—*An un-*
 3 *expired technology certification can be trans-*
 4 *ferred or sold if the transferee or purchaser—*

5 “(i) *is an eligible person under section*
 6 *587D(a)(2); and*

7 “(ii) *maintains, upon such transfer or*
 8 *sale, test design and quality requirements,*
 9 *processes and procedures under the scope of*
 10 *technology certification, and scope of the*
 11 *technology certification identified in the ap-*
 12 *plicable technology certification order.*

13 “(B) *NOTICE REQUIRED.*—*If a developer of*
 14 *an in vitro clinical test transfers or sells a tech-*
 15 *nology certification order that has not expired,*
 16 *the transferor or seller shall submit a notice of*
 17 *the transfer or sale to the Secretary and shall*
 18 *update the registration and listing information*
 19 *under section 587J for all in vitro clinical tests*
 20 *covered by the technology certification.*

21 “(C) *EFFECTIVE DATE OF TECHNOLOGY*
 22 *CERTIFICATION TRANSFER.*—*The transfer of a*
 23 *technology certification shall become effective*
 24 *upon completion of a transfer or sale described*
 25 *in subparagraph (A). The transferee or pur-*

1 *chaser shall update the registration and listing*
 2 *information under section 587J for the in vitro*
 3 *clinical test within 30 calendar days of the effec-*
 4 *tive date of the technology certification transfer.*

5 *“(D) NEW TECHNOLOGY CERTIFICATION RE-*
 6 *QUIRED.—If the requirements of subparagraph*
 7 *(A)(ii) are not met, the technology certification*
 8 *order may not be transferred and the transferee*
 9 *or purchaser of an in vitro clinical test is re-*
 10 *quired to submit an application for technology*
 11 *certification and obtain a technology certifi-*
 12 *cation order prior to offering the test for clinical*
 13 *use.*

14 *“(c) REGULATIONS.—The Secretary may issue regula-*
 15 *tions to implement this subchapter.*

16 **“SEC. 587B. PREMARKET REVIEW.**

17 *“(a) APPLICATION.—*

18 *“(1) FILING.—Any developer may file with the*
 19 *Secretary an application for premarket approval of*
 20 *an in vitro clinical test under this subsection.*

21 *“(2) TRANSPARENCY AND PREDICTABILITY.—If a*
 22 *developer files a premarket application under this sec-*
 23 *tion and provides any additional documentation re-*
 24 *quired under section 587D, the in vitro clinical test*
 25 *that is the subject of the premarket application may*

1 *be utilized as the representative in vitro clinical test*
2 *reviewed by the Secretary to support a technology cer-*
3 *tification order under section 587D.*

4 “(3) *APPLICATION CONTENT.*—An application
5 *submitted under paragraph (1) shall include the fol-*
6 *lowing, in such format as the Secretary specifies:*

7 “(A) *General information regarding the in*
8 *vitro clinical test, including—*

9 “(i) *the name and address of the appli-*
10 *cant;*

11 “(ii) *the table of contents for the appli-*
12 *cation and the identification of the informa-*
13 *tion the applicant claims as trade secret or*
14 *confidential commercial or financial infor-*
15 *mation;*

16 “(iii) *a description of the test’s design*
17 *and intended use, including the indications*
18 *for use; and*

19 “(iv) *a description regarding test func-*
20 *tion and performance characteristics.*

21 “(B) *A summary of the data and informa-*
22 *tion in the application for the in vitro clinical*
23 *test, including—*

24 “(i) *a brief description of the foreign*
25 *and domestic marketing history of the test,*

1 *if any, including a list of all countries in*
2 *which the test has been marketed and a list*
3 *of all countries in which the test has been*
4 *withdrawn from marketing for any reason*
5 *related to the ability of the in vitro clinical*
6 *test to meet the applicable standard, if*
7 *known by the applicant;*

8 “(ii) *a description of benefit and risk*
9 *considerations related to the in vitro clin-*
10 *ical test, including a description of any ap-*
11 *plicable adverse effects of the test on health*
12 *and how such adverse effects have been, or*
13 *will be, mitigated;*

14 “(iii) *a risk assessment of the test; and*

15 “(iv) *a description of how the data and*
16 *information in the application constitute*
17 *valid scientific evidence and support a*
18 *showing that the test meets the applicable*
19 *standard under section 587(2).*

20 “(C) *The signature of the developer filing*
21 *the premarket application or an authorized rep-*
22 *resentative.*

23 “(D) *A bibliography of applicable published*
24 *reports relied upon by the applicant and a de-*
25 *scription of any studies conducted, including*

1 *any unpublished studies related to such test, that*
2 *are known or that should reasonably be known to*
3 *the applicant, and a description of data and in-*
4 *formation relevant to the evaluation of whether*
5 *the test meets the applicable standard.*

6 *“(E) Applicable information regarding the*
7 *methods used in, and the facilities or controls*
8 *used for, the development of the test to dem-*
9 *onstrate compliance with the applicable quality*
10 *requirements under section 587K.*

11 *“(F) Information demonstrating compliance*
12 *with any relevant and applicable—*

13 *“(i) mitigating measures under section*
14 *587E; and*

15 *“(ii) standards established or recog-*
16 *nized under section 514 prior to the date of*
17 *enactment of the VALID Act of 2022, or,*
18 *after applicable standards are established or*
19 *recognized under section 587Q, with such*
20 *standards.*

21 *“(G) Valid scientific evidence to support*
22 *that the test meets the applicable standard,*
23 *which shall include—*

24 *“(i) summary information for all sup-*
25 *porting validation studies performed, in-*

cluding a description of the objective of the study, a description of the experimental design of the study, a description of any limitations of the study, a brief description of how the data were collected and analyzed, a brief description of the results of each study, and conclusions drawn from each study;

“(ii) raw data for each study, which may include, as applicable, tabulations of data and results; and

“(iii) for nonclinical laboratory studies involving the test, if applicable, a statement that studies were conducted in compliance with applicable good laboratory practices.

“(H) To the extent the application seeks authorization to make modifications to the test within the scope of the approval that are not otherwise permitted without premarket review under this subchapter, a proposed change protocol that includes validation procedures and acceptance criteria for anticipated modifications that could be made to the test within the scope of the approval.

“(I) Proposed labeling, in accordance with the requirements of section 587L.

1 “(J) *Such other data or information as the*
2 *Secretary may require in accordance with the*
3 *least burdensome requirements under section*
4 *587AA(c).*

5 “(4) *GUIDANCE FOR PREMARKET AND ABBRE-*
6 *VIATED PREMARKET APPLICATIONS.—In accordance*
7 *with section 825 of the VALID Act of 2022, the Sec-*
8 *retary shall issue draft guidance detailing the infor-*
9 *mation to be provided in a premarket application*
10 *and abbreviated premarket application under this sec-*
11 *tion. The Secretary shall issue final guidance detail-*
12 *ing the information to be provided in a premarket*
13 *application and abbreviated premarket application*
14 *under this section not later than 1 year prior to the*
15 *effective date of such Act.*

16 “(5) *REFUSE TO FILE A PREMARKET OR ABBRE-*
17 *VIATED PREMARKET APPLICATION.—The Secretary*
18 *may refuse to file an application under this section*
19 *only for lack of completeness or legibility of the appli-*
20 *cation. If, after receipt of an application under this*
21 *section, the Secretary refuses to file such an applica-*
22 *tion, the Secretary shall provide to the developer,*
23 *within 45 calendar days of receipt of such application*
24 *submitted under this subsection or within 30 calendar*
25 *days of receipt of an application submitted under*

1 subsection (b), a description of the reason for such re-
 2 fusals, and identify the information required, if any,
 3 to allow for the filing of the application.

4 “(6) *SUBSTANTIVE REVIEW FOR DEFICIENT AP-*
 5 *PLICATION.—If, after receipt of an application under*
 6 *this section, the Secretary determines that any por-*
 7 *tion of such application is materially deficient, the*
 8 *Secretary shall provide to the applicant a description*
 9 *of such material deficiencies and the information re-*
 10 *quired to resolve such deficiencies.*

11 “(7) *INSPECTIONS.—With respect to an applica-*
 12 *tion under paragraph (1), preapproval inspections*
 13 *authorized by an employee of the Food and Drug Ad-*
 14 *ministration or a person accredited under section*
 15 *587Q need not occur unless requested by the Sec-*
 16 *retary.*

17 “(b) *ABBREVIATED PREMARKET REVIEW.—*

18 “(1) *IN GENERAL.—Any developer may file with*
 19 *the Secretary an application for abbreviated pre-*
 20 *market approval for—*

21 “(A) *an instrument;*

22 “(B) *a specimen receptacle;*

23 “(C) *an in vitro clinical test that is mod-*
 24 *erate-risk; or*

1 “(D) *an in vitro clinical test that is deter-*
2 *mined by the Secretary to be eligible for abbrev-*
3 *viated premarket review under section*
4 *587F(a)(1)(B).*

5 “(2) *APPLICATION CONTENT.—An application*
6 *under paragraph (1) shall include—*

7 “(A) *the information required for applica-*
8 *tions submitted under subsection (a)(3), except*
9 *that applications under paragraph (1) need not*
10 *include—*

11 “(i) *quality requirement information;*
12 *or*

13 “(ii) *raw data, unless explicitly re-*
14 *quested by the Secretary; and*

15 “(B) *data, as applicable, to support soft-*
16 *ware validation, electromagnetic compatibility,*
17 *and electrical safety, and information dem-*
18 *onstrating compliance with maintaining quality*
19 *systems documentation.*

20 “(3) *SAFETY INFORMATION.—The developer of an*
21 *in vitro clinical test specimen receptacle reviewed*
22 *under this subsection shall maintain safety informa-*
23 *tion for such specimen receptacle.*

24 “(4) *INSPECTIONS.—With respect to an applica-*
25 *tion under paragraph (1), preapproval inspections*

1 *authorized by an employee of the Food and Drug Ad-*
 2 *ministration or a person accredited under section*
 3 *587Q need not occur unless requested by the Sec-*
 4 *retary.*

5 *“(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—*

6 *“(1) IN GENERAL.—A developer of an instrument*
 7 *family shall file with the Secretary an application for*
 8 *premarket approval of one version of an instrument*
 9 *under this subsection. Any modified versions of the*
 10 *instrument that generate a new instrument within the*
 11 *same instrument family shall be exempt from pre-*
 12 *market review requirements of this section, provided*
 13 *that the developer of such instrument or instrument*
 14 *family—*

15 *“(A) maintains documentation that the new*
 16 *instrument is part of the instrument family, as*
 17 *defined in section 587;*

18 *“(B) performs, documents, and maintains a*
 19 *risk assessment (as described in subsection*
 20 *(a)(3)(B)(iii)) of the new instrument compared*
 21 *to the instrument approved under subsection (b)*
 22 *and no new risks are identified;*

23 *“(C) performs, documents, and maintains*
 24 *validation and verification activities for the new*
 25 *instrument;*

1 “(D) makes such documentation available to
2 the Secretary upon request; and

3 “(E) registers and lists the new instrument
4 in accordance with section 587J.

5 “(2) TEST KITS AND TEST PROTOCOLS.—A test
6 kit or test protocol that is approved under this section
7 for use on an approved instrument or an instrument
8 exempt from premarket review, including an instru-
9 ment within an instrument family under this section,
10 a submission under this section shall not be required
11 for such test kit or test protocol in order for it to be
12 used on a new instrument within its instrument fam-
13 ily, provided that—

14 “(A) use of the test kit or test protocol with
15 the new instrument does not—

16 “(i) change the claims for the test kit
17 or test protocol, except as applicable, claims
18 regarding an instrument or instruments
19 that can be used with such test kit or test
20 protocol;

21 “(ii) adversely affect performance of
22 the test kit or test protocol; or

23 “(iii) cause the test kit or test protocol
24 to no longer conform with performance
25 standards required under section 587R or

1 *comply with any applicable mitigating*
2 *measures under section 587E, conditions of*
3 *approval under subsection (e)(2)(B), or re-*
4 *strictions under section 587O;*

5 *“(B) the test developer does not identify any*
6 *new risks for the test kit or test protocol when*
7 *using the new instrument;*

8 *“(C) the test developer validates the use of*
9 *the new instrument with the test kit or test pro-*
10 *TOCOL and maintains validation documentation;*

11 *“(D) the test kit or test protocol is not in-*
12 *tended for use—*

13 *“(i) in settings for which a certificate*
14 *of waiver is in effect under section 353 of*
15 *the Public Health Service Act;*

16 *“(ii) without a prescription;*

17 *“(iii) at home; or*

18 *“(iv) in testing donors, donations, and*
19 *recipients of blood, blood components,*
20 *human cells, tissues, cellular-based products,*
21 *or tissue-based products;*

22 *“(E) the test developer makes the docu-*
23 *mentation described under subparagraph (C)*
24 *available to the Secretary upon request; and*

1 “(F) the test developer updates the listing
 2 information for the test kit or test protocol, as
 3 applicable.

4 “(d) *AMENDMENTS TO AN APPLICATION.*—An appli-
 5 cant shall amend an application submitted under sub-
 6 section (a), (b), or (f) if the applicant becomes aware of
 7 information that could reasonably affect an evaluation
 8 under subsection (e) of whether the approval standard has
 9 been met.

10 “(e) *ACTION ON AN APPLICATION FOR PREMARKET AP-*
 11 *PROVAL.*—

12 “(1) *REVIEW.*—

13 “(A) *DISPOSITION.*—As promptly as pos-
 14 sible, but not later than 90 calendar days after
 15 an application under subsection (a) is accepted
 16 for submission (unless the Secretary determines
 17 that an extension is necessary to review one or
 18 more major amendments to the application), or
 19 not later than 60 calendar days after an appli-
 20 cation under subsection (b) is accepted for sub-
 21 mission or a supplemental application under
 22 subsection (f) is accepted for submission, the Sec-
 23 retary, after considering any applicable report
 24 and recommendations pursuant to advisory com-
 25 mittees under section 587H, shall issue an order

1 *approving the application, unless the Secretary*
 2 *finds that the grounds for approval in para-*
 3 *graph (2) are not met.*

4 *“(B) RELIANCE ON PROPOSED LABELING.—*
 5 *In determining whether to approve or deny an*
 6 *application under paragraph (1), the Secretary*
 7 *shall rely on the indications for use included in*
 8 *the proposed labeling, provided that such label-*
 9 *ing is not false or misleading based on a fair*
 10 *evaluation of all material facts.*

11 *“(2) APPROVAL OF AN APPLICATION.—*

12 *“(A) IN GENERAL.—The Secretary shall ap-*
 13 *prove an application submitted under subsection*
 14 *(a) or (b) with respect to an in vitro clinical test*
 15 *if the Secretary finds that the applicable stand-*
 16 *ard is met, and—*

17 *“(i) the applicant is in compliance*
 18 *with applicable quality requirements in sec-*
 19 *tion 587K;*

20 *“(ii) the application does not contain*
 21 *a false statement or misrepresentation of*
 22 *material fact;*

23 *“(iii) based on a fair evaluation of all*
 24 *material facts, the proposed labeling is*

1 *truthful and non-misleading and complies*
2 *with the requirements of section 587L;*

3 “(iv) *the applicant permits, if re-*
4 *quested, authorized employees of the Food*
5 *and Drug Administration and persons ac-*
6 *credited under section 587Q an opportunity*
7 *to inspect pursuant to section 704;*

8 “(v) *the test conforms with any appli-*
9 *cable performance standards required under*
10 *section 587R and any applicable mitigating*
11 *measures under section 587E;*

12 “(vi) *all nonclinical laboratory studies*
13 *and clinical investigations involving human*
14 *subjects that are described in the applica-*
15 *tion were conducted in a manner that meets*
16 *the applicable requirements of this sub-*
17 *chapter; and*

18 “(vii) *other data and information the*
19 *Secretary may require under subsection*
20 *(a)(3)(J) support approval.*

21 “(B) *CONDITIONS OF APPROVAL.—An order*
22 *approving an application pursuant to this sec-*
23 *tion may require reasonable conditions of ap-*
24 *proval for the in vitro clinical test, which may*
25 *include conformance with applicable mitigating*

1 *measures under section 587E, restrictions under*
 2 *section 587O, and performance standards under*
 3 *section 587R.*

4 “(C) *PUBLICATION.*—*The Secretary shall*
 5 *publish an order for each application approved*
 6 *pursuant to this paragraph on the public website*
 7 *of the Food and Drug Administration and make*
 8 *publicly available a summary of the data used*
 9 *to approve such application. In making the*
 10 *order and summary publicly available, the Sec-*
 11 *retary shall not disclose any information that—*

12 “(i) *is confidential commercial infor-*
 13 *mation or trade secret information subject*
 14 *to section 552(b)(4) of title 5, United States*
 15 *Code, or section 1905 of title 18, United*
 16 *States Code; or*

17 “(ii) *could compromise national secu-*
 18 *rity.*

19 “(3) *REVIEW OF DENIALS.*—*An applicant whose*
 20 *application submitted under this section has been de-*
 21 *nied approval under this subsection may, by petition*
 22 *filed not more than 60 calendar days after the date*
 23 *on which the applicant receives notice of such denial,*
 24 *obtain review of the denial in accordance with section*
 25 *587P.*

1 “(f) *SUPPLEMENTS TO AN APPROVED APPLICATION.*—

2 “(1) *RISK ANALYSIS.*—Prior to implementing
3 any modification to an in vitro clinical test, the hold-
4 er of the application approved under subsection (e)
5 for such test shall perform risk analyses in accordance
6 with this subsection, unless such modification is in-
7 cluded in the change protocol submitted by the appli-
8 cant and approved under this section or exempt
9 under section 587C.

10 “(2) *SUPPLEMENT REQUIREMENT.*—

11 “(A) *IN GENERAL.*—If the holder of an ap-
12 plication of an approved in vitro clinical test
13 makes a modification to such in vitro clinical
14 test, except as provided in subparagraph (C), or
15 otherwise specified by the Secretary, the holder of
16 the application approved under subsection (e) for
17 an in vitro clinical test shall submit a supple-
18 mental application to the Secretary. The holder
19 of the application may not implement such
20 modification to the in vitro clinical test until
21 such supplemental application is approved. The
22 information required in a supplemental applica-
23 tion is limited to what is needed to support the
24 change.

1 “(B) *ADJUSTMENTS TO CHANGE PRO-*
 2 *TOCOL.—The holder of an approved application*
 3 *may submit under this paragraph a supple-*
 4 *mental application to modify the change protocol*
 5 *of the test at any time after the application is*
 6 *submitted under subsection (a) or (b).*

7 “(C) *EXCEPTIONS.—Notwithstanding sub-*
 8 *paragraphs (A) and (B), and so long as the hold-*
 9 *er of an approved application submitted under*
 10 *subsection (a) or (b) for an in vitro clinical test*
 11 *does not add a manufacturing site, or change ac-*
 12 *tivities at an existing manufacturing site, with*
 13 *respect to the test, the holder of an approved ap-*
 14 *plication may, without submission of a supple-*
 15 *mental application, implement the following*
 16 *modifications to the test:*

17 “(i) *Modifications in accordance with*
 18 *an approved change protocol under sub-*
 19 *section (a)(3)(H).*

20 “(ii) *Modifications that are exempt*
 21 *under section 587C(a)(6).*

22 “(iii) *Labeling changes that are appro-*
 23 *priate to address a safety concern, except*
 24 *such labeling changes that include any of*

1 the following remain subject to subpara-
2 graph (A):

3 “(I) A change to the indications
4 for use of the test.

5 “(II) A change to the performance
6 claims made with respect to the test.

7 “(III) A change that adversely af-
8 fects performance of the test.

9 “(D) *REPORTING FOR CERTAIN MODIFICA-*
10 *TIONS MADE PURSUANT TO A CHANGE PRO-*
11 *TOCOL.—The holder of an application approved*
12 *under subsection (e), with an approved change*
13 *protocol under subsection (a)(2)(H) for such in*
14 *vitro clinical test shall—*

15 “(i) report any modification to such
16 test made pursuant to such change protocol
17 approved under subsection (a)(3)(H) in a
18 submission under section 587J(c)(2)(B);
19 and

20 “(ii) include in such report—

21 “(I) a description of the modifica-
22 tion;

23 “(II) the rationale for imple-
24 menting such modification; and

1 “(III) as applicable, a summary
 2 of the evidence supporting that the test,
 3 as modified, meets the applicable
 4 standard, complies with performance
 5 standards required under section 587Q,
 6 and complies with any mitigating
 7 measures established under section
 8 587E and any restrictions under sec-
 9 tion 587O.

10 “(E) REPORTING FOR CERTAIN SAFETY RE-
 11 LATED LABELING CHANGES.—The holder of the
 12 application for an in vitro clinical test approved
 13 under subsection (e) shall—

14 “(i) report to the Secretary any modi-
 15 fication to the test described in subpara-
 16 graph (C)(iii) not more than 30 days after
 17 the date on which the test, with the modi-
 18 fication, is introduced into interstate com-
 19 merce; and

20 “(ii) include in the report—

21 “(I) a description of the change or
 22 changes;

23 “(II) the rationale for imple-
 24 menting such change or changes; and

1 “(III) a description of how the
2 change or changes were evaluated.

3 “(3) CONTENTS OF SUPPLEMENT.—Unless other-
4 wise specified by the Secretary, a supplement under
5 this subsection shall include—

6 “(A) for modifications other than manufac-
7 turing site changes requiring a supplement—

8 “(i) a description of the modification;

9 “(ii) data relevant to the modification
10 to demonstrate that the applicable standard
11 is met, not to exceed data requirements for
12 the original submission;

13 “(iii) acceptance criteria; and

14 “(iv) any revised labeling; and

15 “(B) for manufacturing site changes—

16 “(i) the information listed in subpara-
17 graph (A); and

18 “(ii) information regarding the meth-
19 ods used in, or the facilities or controls used
20 for, the development of the test to dem-
21 onstrate compliance with the applicable
22 quality requirements under section 587K.

23 “(4) ADDITIONAL DATA.—The Secretary may re-
24 quire, when necessary, data to evaluate a modifica-
25 tion to an in vitro clinical test that is in addition to

1 *the data otherwise required under the preceding para-*
2 *graphs if the data request is in accordance with the*
3 *least burdensome requirements under section*
4 *587AA(c).*

5 “(5) *CONDITIONS OF APPROVAL.*—*In an order*
6 *approving a supplement under this subsection, the*
7 *Secretary may require conditions of approval for the*
8 *in vitro clinical test, including compliance with re-*
9 *strictions under section 587O and conformance to*
10 *performance standards under section 587R.*

11 “(6) *APPROVAL.*—*The Secretary shall approve a*
12 *supplement under this subsection if—*

13 “(A) *the data demonstrate that the modified*
14 *in vitro clinical test meets the applicable stand-*
15 *ard; and*

16 “(B) *the holder of the application approved*
17 *under subsection (e) for the test has demonstrated*
18 *compliance with applicable quality and inspec-*
19 *tion requirements, as applicable and appro-*
20 *priate.*

21 “(7) *PUBLICATION.*—*The Secretary shall publish*
22 *on the public website of the Food and Drug Adminis-*
23 *tration notice of any order approving a supplement*
24 *under this subsection provided that doing so does not*
25 *disclose any information that—*

1 “(A) is trade secret or confidential commer-
2 cial or financial information; or

3 “(B) could compromise national security.

4 “(8) *REVIEW OF DENIAL.*—An applicant whose
5 supplement under this subsection has been denied ap-
6 proval may, by petition filed on or before the 60th
7 calendar day after the date upon which the applicant
8 receives notice of such denial, obtain review of the de-
9 nial in accordance with section 587P.

10 “(g) *WITHDRAWAL AND TEMPORARY SUSPENSION OF*
11 *APPROVAL.*—

12 “(1) *ORDER WITHDRAWING APPROVAL.*—

13 “(A) *IN GENERAL.*—The Secretary may,
14 after providing due notice and an opportunity
15 for an informal hearing to the holder of an ap-
16 proved application for an *in vitro* clinical test
17 under this section, issue an order withdrawing
18 approval of the application if the Secretary finds
19 that—

20 “(i) the grounds for approval under
21 subsection (e) are no longer met;

22 “(ii) there is a reasonable likelihood
23 that the test would cause death or serious
24 adverse health consequences, including by
25 causing the absence, significant delay, or

1 *discontinuation of life-saving or life sus-*
2 *taining medical treatment;*

3 “(iii) *the holder of the approved appli-*
4 *cation—*

5 “(I) *has failed to, or repeatedly or*
6 *deliberately failed to, maintain records*
7 *to make reports, as required under sec-*
8 *tion 587M;*

9 “(II) *has refused to permit access*
10 *to, or copying or verification of such*
11 *records, as required under section 704;*

12 “(III) *has not complied with the*
13 *requirements of section 587K; or*

14 “(IV) *has not complied with any*
15 *mitigating measure required under sec-*
16 *tion 587E or restriction under section*
17 *587O; or*

18 “(iv) *the labeling of such in vitro clin-*
19 *ical test, based on a fair evaluation of all*
20 *material facts, is false or misleading in any*
21 *particular and was not corrected within a*
22 *reasonable time after receipt of written no-*
23 *tice from the Secretary of such fact.*

24 “(B) *CONTENT.—An order under subpara-*
25 *graph (A) withdrawing approval of an applica-*

1 *tion shall state each ground for withdrawal and*
 2 *shall notify the holder of such application 60 cal-*
 3 *endar days prior to issuing such order.*

4 *“(C) PUBLICATION.—The Secretary shall*
 5 *publish any order under subparagraph (A) on*
 6 *the public website of the Food and Drug Admin-*
 7 *istration provided that doing so does not dis-*
 8 *close—*

9 *“(i) any information that is trade se-*
 10 *cret or confidential commercial or financial*
 11 *information; or*

12 *“(ii) any other information that the*
 13 *Secretary determines, if published, could*
 14 *compromise national security.*

15 *“(2) ORDER OF TEMPORARY SUSPENSION.—If,*
 16 *after providing due notice and an opportunity for an*
 17 *informal hearing to the holder of an approved appli-*
 18 *cation for an in vitro clinical test under this section,*
 19 *the Secretary determines, based on scientific evidence,*
 20 *that there is a reasonable likelihood that the in vitro*
 21 *clinical test would cause death or serious adverse*
 22 *health consequences, such as by causing the absence,*
 23 *significant delay, or discontinuation of life-saving or*
 24 *life-sustaining medical treatment, the Secretary shall,*
 25 *by order, temporarily suspend the approval of the ap-*

1 *plication. If the Secretary issues such an order, the*
 2 *Secretary shall proceed expeditiously under para-*
 3 *graph (1) to withdraw approval of such application.*

4 *“(3) APPEAL WITHDRAWING APPROVAL AND OR-*
 5 *DERS OF TEMPORARY SUSPENSIONS.—An order of*
 6 *withdrawal or an order of temporary suspension may*
 7 *be appealed under 587P.*

8 **“SEC. 587C. EXEMPTIONS.**

9 *“(a) IN GENERAL.—The following in vitro clinical*
 10 *tests are exempt from premarket review under section 587B,*
 11 *and may be lawfully marketed subject to other applicable*
 12 *requirements of this Act:*

13 *“(1) TESTS EXEMPT FROM SECTION 510(k).—*

14 *“(A) EXEMPTION.—An in vitro clinical test*
 15 *is exempt from premarket review under section*
 16 *587B and may be lawfully marketed subject to*
 17 *the other applicable requirements of this Act, if*
 18 *the developer of the in vitro clinical test—*

19 *“(i) maintains documentation dem-*
 20 *onstrating that the test meets and continues*
 21 *to meet the criteria set forth in subpara-*
 22 *graph (B); and*

23 *“(ii) makes such documentation avail-*
 24 *able to the Secretary upon request.*

1 “(B) *CRITERIA FOR EXEMPTION.*—An in
2 *vitro* clinical test is exempt as specified in sub-
3 paragraph (A) if such test—

4 “(i)(I)(aa) was offered for clinical use
5 prior to the date of enactment of the *VALID*
6 Act of 2022; and

7 “(bb) immediately prior to such date of
8 enactment was exempt pursuant to sub-
9 section (l) or (m)(2) of section 510 from the
10 requirements for submission of a report
11 under section 510(k); or

12 “(II)(aa) was not offered for clinical
13 use prior to such date of enactment;

14 “(bb) is not an instrument; and

15 “(cc) falls within a category of tests
16 that was exempt from the requirements for
17 submission of a report under section 510(k)
18 as of such date of enactment (including
19 class II devices and excluding class I devices
20 described in section 510(l));

21 “(ii) meets the applicable standard as
22 described in section 587(2);

23 “(iii) is not offered with labeling and
24 advertising that is false or misleading; and

1 “(iv) is not likely to cause or con-
2 tribute to serious adverse health con-
3 sequences.

4 “(C) *EFFECT ON SPECIAL CONTROLS.*—For
5 any in vitro clinical test, or category of in vitro
6 clinical tests, that is exempt from premarket re-
7 view based on the criteria in subparagraph (B),
8 any special control that applied to a device with-
9 in a predecessor category immediately prior to
10 the date of enactment of the *VALID Act* of 2022
11 shall be deemed a mitigating measure applicable
12 under section 587E to an in vitro clinical test
13 within the successor category, except to the extent
14 such mitigating measure is withdrawn or
15 changed in accordance with section 587E.

16 “(D) *NEAR-PATIENT TESTING.*—Not later
17 than 1 year after the date of enactment of the
18 *VALID Act* of 2022, the Secretary shall issue
19 draft guidance indicating categories of tests that
20 shall be exempt from premarket review under
21 section 587B when offered for near-patient test-
22 ing (point of care), which were not exempt from
23 submission of a report under section 510(k) pur-
24 suant to subsection (l) or (m)(2) of section 510
25 and regulations imposing limitations on exemp-

1 *tion for in vitro devices intended for near-pa-*
 2 *tient testing (point of care).*

3 “(2) *LOW-RISK TESTS.*—

4 “(A) *EXEMPTION.*—*An in vitro clinical test*
 5 *is exempt from premarket review under section*
 6 *587B and may be lawfully marketed subject to*
 7 *the other applicable requirements of this Act, in-*
 8 *cluding section 587J(b), if such test meets the*
 9 *definition of low-risk under section 587 and if*
 10 *the developer of the test—*

11 “(i) *maintains documentation dem-*
 12 *onstrating that the in vitro clinical test*
 13 *meets and continues to meet the criteria set*
 14 *forth in subparagraph (B); and*

15 “(ii) *makes such documentation avail-*
 16 *able to the Secretary upon request.*

17 “(B) *CRITERIA FOR EXEMPTION.*—*An in*
 18 *vitro clinical test is exempt as specified in sub-*
 19 *paragraph (A) if—*

20 “(i) *the in vitro clinical test meets the*
 21 *applicable standard as described in 587(2);*

22 “(ii) *the labeling and advertising are*
 23 *not false or misleading;*

1 “(iii) *the in vitro clinical test is not*
2 *likely to cause or contribute to serious ad-*
3 *verse health consequences; and*

4 “(iv) *the in vitro clinical test falls*
5 *within a category of tests listed as described*
6 *in subparagraph (C).*

7 “(C) *LIST OF LOW-RISK TESTS.—*

8 “(i) *IN GENERAL.—The Secretary shall*
9 *maintain, and make publicly available on*
10 *the website of the Food and Drug Adminis-*
11 *tration, a list of in vitro clinical tests, and*
12 *categories of in vitro clinical tests, that are*
13 *low-risk in vitro clinical tests for purposes*
14 *of the exemption under this paragraph.*

15 “(ii) *INCLUSION.—The list under*
16 *clause (i) shall consist of—*

17 “(I) *all in vitro clinical tests and*
18 *categories of in vitro clinical tests that*
19 *are exempt from premarket review pur-*
20 *suant to paragraph (1) or this para-*
21 *graph; and*

22 “(II) *all in vitro clinical tests and*
23 *categories of in vitro clinical tests that*
24 *are designated by the Secretary pursu-*

1 *ant to subparagraph (D) as low-risk*
2 *for purposes of this paragraph.*

3 “(D) *DESIGNATION OF TESTS AND CAT-*
4 *EGORIES.—Without regard to subchapter II of*
5 *chapter 5 of title 5, United States Code, the Sec-*
6 *retary may designate, in addition to the tests*
7 *and categories described in subparagraph (C)(i),*
8 *additional in vitro clinical tests, and categories*
9 *of in vitro clinical tests, as low-risk in vitro clin-*
10 *ical tests for purposes of the exemption under*
11 *this paragraph. The Secretary may make such a*
12 *designation on the Secretary’s own initiative or*
13 *in response to a request by a developer pursuant*
14 *to subsection (a) or (b) of section 587F. In mak-*
15 *ing such a designation for a test or category of*
16 *tests, the Secretary shall consider—*

17 “(i) *whether the test, or category of*
18 *tests, is low-risk;*

19 “(ii) *the existence of and ability to de-*
20 *velop mitigating measures sufficient for*
21 *such test category to meet the low-risk*
22 *standard; and*

23 “(iii) *such other factors as the Sec-*
24 *retary determines to be appropriate for the*
25 *protection of the public health.*

1 “(3) *HUMANITARIAN TEST EXEMPTION.*—

2 “(A) *IN GENERAL.*—*An in vitro clinical test*
 3 *that meets the criteria under subparagraph (B)*
 4 *is exempt from premarket review under section*
 5 *587B and may be lawfully offered subject to the*
 6 *other applicable requirements of this subchapter,*
 7 *if the developer of the test—*

8 “(i) *maintains documentation (which*
 9 *may include literature citations in special-*
 10 *ized medical journals, textbooks, specialized*
 11 *medical society proceedings, and govern-*
 12 *mental statistics publications, or, if no such*
 13 *studies or literature citations exist, credible*
 14 *conclusions from appropriate research or*
 15 *surveys) demonstrating that such test meets*
 16 *and continues to meet the criteria described*
 17 *in this subsection; and*

18 “(ii) *makes such documentation avail-*
 19 *able to the Secretary upon request.*

20 “(B) *CRITERIA FOR EXEMPTION.*—*An in*
 21 *vitro clinical test is exempt as described in sub-*
 22 *paragraph (A) if—*

23 “(i) *the in vitro clinical test is in-*
 24 *tended by the developer for use for a diag-*
 25 *nostic purpose for a disease or condition*

1 that affects not more than 10,000 (or such
2 other higher number determined by the Sec-
3 retary) individuals in the United States per
4 year;

5 “(ii) the *in vitro* clinical test meets the
6 applicable standard described in section
7 587(2);

8 “(iii) the labeling and advertising for
9 the *in vitro* clinical test are not false or
10 misleading;

11 “(iv) the *in vitro* clinical test is not
12 likely to cause or contribute to serious ad-
13 verse health consequences; and

14 “(v) the *in vitro* clinical test is not in-
15 tended for screening.

16 “(C) *EXCEPTION FOR CERTAIN TESTS.*—An
17 *in vitro* clinical test intended to inform the use
18 of a specific individual or specific type of bio-
19 logical product, drug, or device shall be eligible
20 for an exemption from premarket review under
21 this subsection only if, the developer submits a
22 request under section 587F(e) for informal feed-
23 back and the Secretary determines that such *in*
24 *vitro* clinical test is eligible for an exemption
25 from premarket review under this subsection.

1 “(4) *CUSTOM TESTS AND LOW-VOLUME TESTS.*—
2 *An in vitro clinical test is exempt from premarket re-*
3 *view under section 587B, quality requirements under*
4 *section 587K, and listing requirements under section*
5 *587J, and may be lawfully marketed subject to the*
6 *other applicable requirements of this Act, if—*

7 “(A) *such in vitro clinical test—*

8 “(i) *is a test protocol performed for not*
9 *more than 5 patients per year (or such*
10 *other higher number determined by the Sec-*
11 *retary), in a laboratory certified by the Sec-*
12 *retary under section 353 of the Public*
13 *Health Service Act that—*

14 “(I) *meets the requirements to*
15 *perform tests of high-complexity in*
16 *which the test protocol was developed;*
17 *or*

18 “(II) *meets the requirements to*
19 *perform tests of high-complexity within*
20 *the same corporate organization and*
21 *having common ownership by the same*
22 *parent corporation as the laboratory in*
23 *which such test protocol was developed;*
24 *or*

1 “(ii) is an *in vitro* clinical test devel-
2 oped or modified to diagnose a unique pa-
3 thology or physical condition of a specific
4 patient or patients, upon order of a health
5 professional or other specially qualified per-
6 son designated under regulations, for which
7 no other *in vitro* clinical test is commer-
8 cially available in the United States, and
9 is—

10 “(I) not intended for use with re-
11 spect to more than 5 (or such other
12 higher number determined by the Sec-
13 retary) other patients; and

14 “(II) after the development of such
15 test, not included in any test menu or
16 template test report or other pro-
17 motional materials, and is not other-
18 wise advertised; and

19 “(B) the developer of the *in vitro* clinical
20 test—

21 “(i) maintains documentation dem-
22 onstrating that such test meets the applica-
23 ble criteria described in subparagraph (A);

24 “(ii) makes such documentation, such
25 as a prescription order requesting the cus-

1 *tom test for an individual patient, available*
 2 *to the Secretary upon request; and*

3 *“(iii) informs the Secretary, on an an-*
 4 *nual basis, in a manner prescribed by the*
 5 *Secretary by guidance, that such test was*
 6 *offered.*

7 *“(5) IN VITRO CLINICAL TESTS UNDER A TECH-*
 8 *NOLOGY CERTIFICATION ORDER.—An in vitro clinical*
 9 *test that is within the scope of a technology certifi-*
 10 *cation order, as described in section 587D(a), is ex-*
 11 *empt from premarket review under section 587B.”.*

12 *“(6) MODIFIED TESTS.—*

13 *“(A) IN GENERAL.—An in vitro clinical test*
 14 *that is modified is exempt from premarket re-*
 15 *view under section 587B if—*

16 *“(i) the modification is made by—*

17 *“(I) the developer that obtained*
 18 *premarket approval for the unmodified*
 19 *version of the test under section 587B;*
 20 *or*

21 *“(II) a clinical laboratory cer-*
 22 *tified by the Secretary under section*
 23 *353 of the Public Health Service Act*
 24 *that meets the requirements for per-*
 25 *forming high complexity testing, to a*

1 *lawfully offered in vitro clinical test,*
2 *including another developer's lawfully*
3 *offered in vitro clinical test, excluding*
4 *investigational in vitro clinical tests*
5 *offered under section 587S, and the*
6 *modified test is performed—*

7 *“(aa) in the same clinical*
8 *laboratory in which it was devel-*
9 *oped for which a certification is*
10 *still in effect under section 353*
11 *that meets the requirements to*
12 *perform tests of high complexity;*

13 *“(bb) by another clinical lab-*
14 *oratory for which a certificate is*
15 *in effect under section 353 that*
16 *meets the requirements to perform*
17 *tests of high complexity, is within*
18 *the same corporate organization,*
19 *and has common ownership by the*
20 *same parent corporation as the*
21 *laboratory in which the test was*
22 *developed; or*

23 *“(cc) by a clinical laboratory*
24 *for which a certificate is in effect*
25 *under section 353 that meets the*

1 *requirements to perform tests of*
2 *high complexity and is within a*
3 *public health laboratory network*
4 *coordinated or managed by the*
5 *Centers for Disease Control and*
6 *Prevention, if the test was devel-*
7 *oped by the Centers for Disease*
8 *Control and Prevention or an-*
9 *other laboratory within such pub-*
10 *lic health laboratory network; and*

11 *“(ii) the modification does not—*

12 *“(I) constitute a significant*
13 *change to the indications for use;*

14 *“(II) cause the test to no longer*
15 *comply with applicable mitigating*
16 *measures under section 587E or re-*
17 *strictions under section 587O;*

18 *“(III) significantly and adversely*
19 *change performance claims or signifi-*
20 *cantly and adversely change perform-*
21 *ance, unless provided for under an ap-*
22 *proved change protocol under section*
23 *587B(a)(3)(H); or*

24 *“(IV) constitute an adverse change*
25 *in the safety of the in vitro clinical test*

1 *for individuals who come in contact*
2 *with the in vitro clinical test;*

3 “(iii) *the test meets the applicable*
4 *standard as described in section 587(2);*

5 “(iv) *the labeling and advertising are*
6 *not false or misleading; and*

7 “(v) *the test is not likely to cause or*
8 *contribute to serious adverse health con-*
9 *sequences.*

10 “(B) *CERTAIN MODIFICATIONS.—A modi-*
11 *fication to extend specimen stability is exempt*
12 *from premarket review under section 587B if the*
13 *modified test meets the requirements in clauses*
14 *(ii) through (iv) of subparagraph (A).*

15 “(C) *MODIFICATIONS UNDER A CHANGE*
16 *PROTOCOL.—Notwithstanding subparagraph (A),*
17 *a modification made under a change protocol*
18 *pursuant to subsection (a)(2)(H) of section 587B*
19 *is exempt from review under such section.*

20 “(D) *DOCUMENTATION.—A person who*
21 *modifies an in vitro clinical test in a manner*
22 *that is a modification described in subparagraph*
23 *(A) shall—*

24 “(i) *document the modification that*
25 *was made and the basis for determining*

1 that the modification, considering the
 2 changes individually and collectively, is a
 3 type of modification described in subpara-
 4 graph (A), (B), or (C); and

5 “(ii) provide such documentation to
 6 the Secretary upon request or inspection.

7 “(E) *GUIDANCE*.—Not later than 30 months
 8 after the date of enactment of the *VALID Act* of
 9 2022, the Secretary shall issue guidance regard-
 10 ing the *in vitro* clinical tests that are modified
 11 and exempt from premarket review under section
 12 587B pursuant to this paragraph.

13 “(b) *MANUAL TESTS*.—

14 “(1) *EXEMPTION*.—An *in vitro* clinical test is
 15 exempt from all requirements of this subchapter if the
 16 output of such *in vitro* clinical test is the result of di-
 17 rect, manual observation, without the use of auto-
 18 mated instrumentation or software for intermediate
 19 or final interpretation, by a qualified laboratory pro-
 20 fessional, and such *in vitro* clinical test—

21 “(A) is developed and used within a single
 22 clinical laboratory for which a certificate is in
 23 effect under section 353 of the *Public Health*
 24 *Service Act* that meets the requirements under

1 *section 353 for performing high-complexity test-*
 2 *ing;*

3 *“(B) is not a specimen receptacle, instru-*
 4 *ment, or an in vitro clinical test that includes*
 5 *an instrument or specimen receptacle that is not*
 6 *approved under or exempt from section 587B;*

7 *“(C) is not a high-risk test, or is a high-risk*
 8 *test that the Secretary has determined meets at*
 9 *least one condition in paragraph (2) and is oth-*
 10 *erwise appropriate for this exemption; and*

11 *“(D) is not intended for testing donors, do-*
 12 *nations, or recipients of blood, blood components,*
 13 *human cells, tissues, cellular-based products, or*
 14 *tissue-based products.*

15 *“(2) HIGH-RISK TEST LIMITATION OR CONDI-*
 16 *TION.—A high-risk test may be exempt under para-*
 17 *graph (1) from the requirements of this subchapter*
 18 *only if—*

19 *“(A) no components or parts of such test,*
 20 *including any reagent, is introduced into inter-*
 21 *state commerce under the exemption under sub-*
 22 *section (e), and any article for taking or deriv-*
 23 *ing specimens from the human body used in con-*
 24 *junction with the test remains subject to the re-*
 25 *quirements of this subchapter; or*

1 “(B) the test has been developed in accord-
 2 ance with the applicable test design and quality
 3 requirements under section 587K.

4 “(c) *PUBLIC HEALTH SURVEILLANCE ACTIVITIES.*—

5 “(1) *IN GENERAL.*—The provisions of this sub-
 6 chapter shall not apply to a test intended by the de-
 7 veloper to be used solely for public health surveillance
 8 activities.

9 “(2) *EXCLUSION.*—An *in vitro* clinical test used
 10 for public health surveillance activities is not excluded
 11 from the provisions of this subchapter pursuant to
 12 this subsection if such test is intended for use in mak-
 13 ing clinical decisions for individual patients.

14 “(d) *GENERAL LABORATORY EQUIPMENT.*—Any *in-*
 15 strument that does not produce an analytical result, and
 16 that functions as a component of pre-analytical procedures
 17 related to *in vitro* clinical tests, is not subject to the require-
 18 ments of this subchapter, provided that the instrument is
 19 operating in a clinical laboratory that is certified under
 20 section 353 of the Public Health Service Act.

21 “(e) *COMPONENTS AND PARTS.*—

22 “(1) *IN GENERAL.*—Subject to paragraph (2), a
 23 component or part described in section 201(ss)(2)(G)
 24 is—

1 “(A) exempt from the requirements of this
 2 subchapter if it is intended for further develop-
 3 ment as described in paragraph (3); or

4 “(B) subject to the requirements of this sub-
 5 chapter and regulated based on its risk when
 6 used as intended by the developer, notwith-
 7 standing its subsequent use by a developer as a
 8 component, part, or raw material of another in
 9 vitro clinical test.

10 “(2) *INAPPLICABILITY TO OTHER TESTS.*—Not-
 11 withstanding paragraph (1), an in vitro clinical test
 12 that is described in section 201(ss)(1)(B) and that
 13 uses a component or part described in such subpara-
 14 graph shall be subject to the requirements of this sub-
 15 chapter, unless the test is otherwise exempt under this
 16 section.

17 “(3) *FURTHER DEVELOPMENT.*—A component,
 18 part, or raw material (as described in paragraph (1))
 19 is intended for further development (for purposes of
 20 such paragraph) if—

21 “(A) it is intended solely for use in the de-
 22 velopment of another in vitro clinical test; and

23 “(B) in the case of such a test that is intro-
 24 duced or delivered for introduction into inter-
 25 state commerce after the date of enactment of the

1 *VALID Act of 2022, the labeling of such test*
 2 *bears the following statement: ‘This product is*
 3 *intended solely for further development of an in*
 4 *vitro clinical test and is exempt from FDA regu-*
 5 *lation. This product must be evaluated by the in*
 6 *vitro clinical test developer if it is used with or*
 7 *in the development of an in vitro clinical test.’.*

8 “(f) *GENERAL EXEMPTION AUTHORITY.*—*The Sec-*
 9 *retary may, by order published in the Federal Register fol-*
 10 *lowing notice and an opportunity for comment, exempt a*
 11 *class of persons from any section under this subchapter*
 12 *upon a finding that such exemption is appropriate for the*
 13 *protection of the public health and other relevant consider-*
 14 *ations.*

15 “(g) *EXEMPTION.*—*An in vitro clinical test that is in-*
 16 *tended solely for use in forensic analysis or law enforcement*
 17 *activity is exempt from the requirements of this subchapter.*
 18 *An in vitro clinical test that is intended for use in making*
 19 *clinical decisions for individual patients, or whose individ-*
 20 *ually identifiable results may be reported back to an indi-*
 21 *vidual patient or the patient’s health care provider, even*
 22 *if also intended for forensic analysis or law enforcement*
 23 *purposes, is not intended solely for forensic analysis or law*
 24 *enforcement for purposes of this subsection.*

25 “(h) *REVOCATION.*—

1 “(1) *IN GENERAL.*—*The Secretary may revoke*
2 *any exemption under this section with respect to in*
3 *vitro clinical tests with the same indications for use*
4 *if new clinical information indicates that the exemp-*
5 *tion of an in vitro clinical test or tests from pre-*
6 *market review under section 587B has a reasonable*
7 *probability of severe adverse health consequences, in-*
8 *cluding the absence, delay, or discontinuation of ap-*
9 *propriate medical treatment.*

10 “(2) *PROCESS.*—*Any action under paragraph*
11 *(1) shall be made by publication of a notice of such*
12 *proposed action on the website of the Food and Drug*
13 *Administration, the consideration of comments to a*
14 *public docket on such proposal, and publication of a*
15 *final action on such website within 60 calendar days*
16 *of the close of the comment period posted to such pub-*
17 *lic docket, notwithstanding subchapter II of chapter 5*
18 *of title 5, United States Code.*

19 “(i) *PRE-ANALYTICAL INSTRUMENT.*—*A pre-analyt-*
20 *ical instrument is exempt from premarket review under sec-*
21 *tion 587B and may be lawfully offered subject to the other*
22 *applicable requirements of this Act, if either of the following*
23 *applies:*

24 “(1) *Such instrument provides additional infor-*
25 *mation regarding the sample or performs an action*

1 on the sample but is not preparing or processing the
 2 sample and does not perform any function of an ana-
 3 lytical instrument. Such types of pre-analytical in-
 4 struments include barcode readers, sample movers,
 5 and sample identifiers.

6 “(2) Such instrument processes or prepares the
 7 sample prior to use on an analytical instrument, does
 8 not perform any function of an analytical instru-
 9 ment, and does not select, isolate, or prepare a part
 10 of a sample based on specific properties. Such types
 11 of pre-analytical instruments may include sample
 12 mixers, DNA extractors and those used to dilute sam-
 13 ples.

14 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

15 “(a) *DEFINITIONS.*—In this section:

16 “(1) *ELIGIBLE IN VITRO CLINICAL TEST.*—The
 17 term ‘eligible in vitro clinical test’ means an in vitro
 18 clinical test that is not—

19 “(A) a component or part of an in vitro
 20 clinical test as described in section 201(ss)(2)(G)
 21 unless it is a component or part and is regulated
 22 based on its own risk under section
 23 587C(e)(1)(B) or as part of an otherwise eligible
 24 in vitro clinical test;

1 “(B) an instrument under section
2 201(ss)(2)(D) or an *in vitro* clinical test that in-
3 cludes an instrument that is subject to section
4 587B, but is not approved under, or exempt
5 from, section 587B;

6 “(C) a specimen receptacle under section
7 201(ss)(2)(E) or an *in vitro* clinical test that in-
8 cludes a specimen receptacle that is subject to
9 section 587B, but is not approved under, or ex-
10 empt from, section 587B;

11 “(D) an *in vitro* clinical test, including re-
12 agents used in such tests, intended for use for
13 testing donors, donations, and recipients of
14 blood, blood components, human cells, tissues,
15 cellular-based products, or tissue-based products;

16 “(E) high-risk;

17 “(F) a combination product unless such test
18 has been determined to be eligible to be intro-
19 duced into interstate commerce under a tech-
20 nology certification order pursuant to the regu-
21 latory pathway designation process described in
22 section 587F, or as described in subsection (k);
23 or

24 “(G) a first-of-a-kind *in vitro* clinical test,
25 unless such test has been determined to be eligible

1 *to be introduced into interstate commerce under*
2 *a technology certification order pursuant to the*
3 *regulatory pathway designation process described*
4 *in section 587F, or as described in subsection*
5 *(k).*

6 “(2) *ELIGIBLE PERSON.*—*The term ‘eligible per-*
7 *son’ means an in vitro clinical test developer unless*
8 *such developer—*

9 “(A) *is a laboratory subject to section 353*
10 *of the Public Health Service Act and does not*
11 *have in effect a certificate applicable to the cat-*
12 *egory of laboratory examination or other proce-*
13 *dure;*

14 “(B) *was a laboratory, or an owner or oper-*
15 *ator or any employee of a laboratory, found to*
16 *have committed a significant violation of section*
17 *353 of the Public Health Service Act that re-*
18 *sulted in a suspended, revoked, or limited certifi-*
19 *cate within the 2-year period preceding the date*
20 *of the submission of the application for a tech-*
21 *nology certificate under subsection (c) and such*
22 *violation has not been resolved; or*

23 “(C) *has been found to have submitted in-*
24 *formation to the Secretary, or otherwise dissemi-*
25 *nated information, that—*

1 “(i) made false or misleading state-
2 ments relevant to the requirements of this
3 subchapter; or

4 “(ii) violated any requirement of this
5 Act, where such violation exposed individ-
6 uals to serious risk of illness, injury, or
7 death, unless—

8 “(I) such violation has been re-
9 solved; or

10 “(II) such violation is not perti-
11 nent to any in vitro clinical test with-
12 in the scope of the technology certifi-
13 cation that such developer seeks.

14 “(b) *APPLICABILITY.*—

15 “(1) *IN GENERAL.*—An in vitro clinical test is
16 not subject to section 587B and may be introduced
17 into interstate commerce if the in vitro clinical test—

18 “(A) is an eligible in vitro clinical test;

19 “(B) is developed by an eligible person;

20 “(C) falls within the scope of a technology
21 certification order issued under this section and
22 that is in effect;

23 “(D) complies with the conditions of the
24 technology certification order, including with ap-
25 plicable mitigating measures under section

587E, restrictions under section 587O, and performance standards under section 587R; and

“(E) meets the applicable standard described in section 587(2).

“(2) SCOPE.—

“(A) IN GENERAL.—Subject to subparagraph (B), the scope of a technology certification order issued under this section shall apply to one or more technologies with multiple in vitro clinical tests utilizing a technology that does not significantly differ in control mechanisms, energy sources, or operating principles and for which development, including design, and analytical and clinical validation, of the in vitro clinical tests would be addressed through similar procedures, and be no broader than—

“(i) a single technology type; or

“(ii) a fixed combination of technologies.

“(B) TECHNOLOGY TYPE.—A technology type described in this paragraph may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spec-

1 *trometry or chromatography, microbial culture,*
 2 *next generation sequencing, nephelometric or tur-*
 3 *bidimetric (non-immunoassay), singleplex or*
 4 *multiplex non-NGS nucleic acid analysis, slide-*
 5 *based technology, spectroscopy, and any other*
 6 *technology, as the Secretary determines appro-*
 7 *priate.*

8 “(c) *APPLICATION FOR TECHNOLOGY CERTIFI-*
 9 *CATION.—*

10 “(1) *IN GENERAL.—A developer seeking a tech-*
 11 *nology certification order shall submit an application*
 12 *under this subsection, which shall contain the infor-*
 13 *mation specified under paragraph (2).*

14 “(2) *CONTENT OF APPLICATION.—A developer*
 15 *that submits an application for a technology certifi-*
 16 *cation shall include all necessary information to make*
 17 *a showing that all eligible in vitro clinical tests devel-*
 18 *oped within the scope of the technology certification*
 19 *order will meet the applicable standard, including—*

20 “(A) *the name and address of the developer;*

21 “(B) *a table of contents for the application*
 22 *and the identification of the information the de-*
 23 *veloper claims as trade secret or confidential*
 24 *commercial or financial information;*

1 “(C) the signature of the individual filing
2 the application or an authorized representative;

3 “(D) a statement identifying the scope of
4 the proposed technology certification intended to
5 be introduced into interstate commerce under the
6 application;

7 “(E) information establishing that the de-
8 veloper submitting the application is an eligible
9 person;

10 “(F) quality procedures showing that eligi-
11 ble in vitro clinical tests covered under the tech-
12 nology certification will conform to the applica-
13 ble quality requirements of section 587K with re-
14 spect to—

15 “(i) design controls, including related
16 purchasing controls and acceptance activi-
17 ties;

18 “(ii) complaint investigation, adverse
19 event reporting, and corrections and remov-
20 als; and

21 “(iii) process validation, as applicable;

22 “(G) procedures for analytical and clinical
23 validation, including all procedures for valida-
24 tion, verification, and acceptance criteria, and
25 an explanation as to how such procedures, when

1 *used, provide a showing that eligible in vitro*
2 *clinical tests within the proposed scope of the*
3 *technology certification order are analytically*
4 *and clinically valid;*

5 *“(H) procedures that provide a showing*
6 *that in vitro clinical tests covered by the pro-*
7 *posed scope of the technology certification order*
8 *will be safe for individuals who come into con-*
9 *tact with in vitro clinical tests covered by such*
10 *order;*

11 *“(I) a proposed listing submission under*
12 *section 587J(b) for in vitro clinical tests that the*
13 *developer intends to introduce into interstate*
14 *commerce upon receiving a technology certifi-*
15 *cation order, which shall not be construed to*
16 *limit the developer from introducing additional*
17 *tests not included in such submission under the*
18 *same technology certification order;*

19 *“(J) information concerning one or more*
20 *representative in vitro clinical tests, including—*

21 *“(i) a test within the scope of the tech-*
22 *nology certification application with the*
23 *appropriate analytical complexity at the*
24 *time of the submission of the application*

1 *under this section to serve as the representa-*
2 *tive test;*

3 “(ii) *the information specified in sub-*
4 *section (a) or (b) of section 587B, as appli-*
5 *cable, for the representative in vitro clinical*
6 *test or tests, including information and*
7 *data required pursuant to subsection*
8 *(a)(2)(G) of section 587B, unless the Sec-*
9 *retary determines that such information is*
10 *not necessary;*

11 “(iii) *a summary of a risk assessment*
12 *of the in vitro clinical test;*

13 “(iv) *an explanation of the choice of*
14 *the representative in vitro clinical test or*
15 *tests for the technology certification applica-*
16 *tion and how such test adequately dem-*
17 *onstrates the range of procedures that the*
18 *developer includes in the application under*
19 *subparagraphs (F), (G), (H), and (I); and*

20 “(v) *a brief explanation of the ways in*
21 *which the procedures included in the appli-*
22 *cation under subparagraphs (F), (G), (H),*
23 *and (I) have been applied to the representa-*
24 *tive in vitro clinical test or tests; and*

1 “(K) such other information necessary to
 2 make a determination on a technology certifi-
 3 cation application as the Secretary may deter-
 4 mine necessary.

5 “(3) REFERENCE TO EXISTING APPLICATIONS.—
 6 With respect to the content requirements in the tech-
 7 nology certification application described in para-
 8 graph (2), a developer may incorporate by reference
 9 any content of an application previously submitted
 10 by the developer.

11 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY
 12 CERTIFICATION.—

13 “(1) SECRETARY RESPONSE.—

14 “(A) IN GENERAL.—As promptly as prac-
 15 ticable, and not later than 90 days after receipt
 16 of an application under subsection (c), the Sec-
 17 retary shall—

18 “(i) issue a technology certification
 19 order granting the application, which shall
 20 specify the scope of the technology certifi-
 21 cation, if the Secretary finds that all of the
 22 grounds in paragraph (3) are met; or

23 “(ii) deny the application if the Sec-
 24 retary finds (and sets forth the basis of such
 25 finding as part of or accompanying such

1 *denial) that one or more grounds for grant-*
 2 *ing the application specified in paragraph*
 3 *(3) are not met.*

4 “(B) *EXTENSION.*—*The timeline described*
 5 *in subparagraph (A) may be extended by mutual*
 6 *agreement between the Secretary and the appli-*
 7 *cant.*

8 “(2) *DEFICIENT APPLICATIONS.*—

9 “(A) *IN GENERAL.*—*If, after receipt of an*
 10 *application under this section, the Secretary de-*
 11 *termines that any portion of such application is*
 12 *deficient, the Secretary, not later than 60 days*
 13 *after receipt of such application, shall provide to*
 14 *the applicant a description of such deficiencies*
 15 *and identify the information required to resolve*
 16 *such deficiencies.*

17 “(B) *CONVERTING TO PREMARKET APPLICA-*
 18 *TIONS.*—*When responding to the deficiency letter,*
 19 *the developer may convert the application for*
 20 *technology certification under subsection (c) into*
 21 *a premarket application under section 587B.*

22 “(3) *TECHNOLOGY CERTIFICATION ORDER.*—*The*
 23 *Secretary shall issue an order granting a technology*
 24 *certification under this section if, on the basis of the*
 25 *information submitted to the Secretary as part of the*

1 *application and any other information with respect*
2 *to such applicant, the Secretary finds that—*

3 “(A) *there is a showing that in vitro clin-*
4 *ical tests within the scope of the technology cer-*
5 *tification order will meet the applicable stand-*
6 *ard;*

7 “(B) *the methods used in, and the facilities*
8 *or controls used for, the development of eligible*
9 *in vitro clinical tests covered by the proposed*
10 *scope of the technology certification conform to*
11 *the applicable requirements of section 587K with*
12 *respect to—*

13 “(i) *design controls, including related*
14 *purchasing controls and acceptance activi-*
15 *ties;*

16 “(ii) *complaint investigation, adverse*
17 *event reporting, and corrections and remov-*
18 *als; and*

19 “(iii) *process validation, as applicable;*

20 “(C) *based on a fair evaluation of all mate-*
21 *rial facts, the applicant’s proposed labeling and*
22 *advertising are not false or misleading in any*
23 *particular;*

24 “(D) *the application does not contain a*
25 *false statement of material fact;*

1 “(E) there is a showing that the representa-
2 tive in vitro clinical test or tests—

3 “(i) meet the applicable standard; and

4 “(ii) reasonably represent the range of
5 procedures required to be submitted in the
6 application;

7 “(F) the applicant has agreed to permit,
8 upon request, authorized employees of the Food
9 and Drug Administration or persons accredited,
10 or recognized under this Act, an opportunity to
11 inspect at a reasonable time and in a reasonable
12 manner the facilities and all pertinent equip-
13 ment, finished and unfinished materials, con-
14 tainers, and labeling therein, including all
15 things (including records, files, papers, and con-
16 trols) bearing on whether an in vitro clinical test
17 is adulterated, misbranded, or otherwise in viola-
18 tion of this Act, and permits such authorized em-
19 ployees or persons accredited under this Act to
20 view and to copy and verify all records pertinent
21 to the application and the in vitro clinical test;
22 and

23 “(G) based on other data and information
24 the Secretary may require under subsection
25 (c)(2)(K), the Secretary finds that such data and

1 *information support granting a technology cer-*
2 *tification order.*

3 “(4) *REVIEW OF DENIALS.*—*An applicant whose*
4 *application has been denied under this subsection*
5 *may obtain review of such denial under section 587P.*

6 “(e) *SUPPLEMENTS.*—

7 “(1) *SUPPLEMENTAL APPLICATIONS.*—

8 “(A) *IN GENERAL.*—*With respect to any of*
9 *the following changes related to an in vitro clin-*
10 *ical test under a technology certification order, a*
11 *supplemental application to a technology certifi-*
12 *cation order shall be submitted by the holder of*
13 *the technology certification order describing such*
14 *proposed changes, prior to introducing the in*
15 *vitro clinical test that is the subject of the tech-*
16 *nology certification order into interstate com-*
17 *merce—*

18 “(i) *any significant change to the pro-*
19 *cedures provided in support of the applica-*
20 *tion for technology certification submitted*
21 *under subparagraph (G) or (H) of sub-*
22 *section (c)(2); or*

23 “(ii) *any significant change to the pro-*
24 *cedures provided in support of the applica-*
25 *tion for technology certification submitted*

1 under subparagraph (F) of subsection
2 (c)(2).

3 “(B) SECRETARY ACTION ON SUPPLE-
4 MENTAL APPLICATIONS.—Any action by the Sec-
5 retary on a supplemental application shall be in
6 accordance with subsection (d), and any order
7 resulting from such supplement shall be treated
8 as an amendment to a technology certification
9 order.

10 “(2) CONTENT OF APPLICATION.—

11 “(A) IN GENERAL.—A supplemental appli-
12 cation for a change to an in vitro clinical test
13 under a technology certification order shall—

14 “(i) contain all necessary information
15 to make a showing that any in vitro clin-
16 ical test affected by such change that is
17 within the scope of the technology certifi-
18 cation order will meet the applicable stand-
19 ard; and

20 “(ii) be limited to such information
21 that is needed to support the change.

22 “(B) CONTENT.—Unless otherwise specified
23 by the Secretary, a supplemental application
24 under this subsection shall include—

1 “(i) a description of the change, in-
2 cluding a rationale for implementing such
3 change;

4 “(ii) a description of how the change
5 was evaluated;

6 “(iii) data from a representative in
7 vitro clinical test or tests that supports a
8 showing that, in using the modified proce-
9 dure or procedures, all eligible in vitro clin-
10 ical tests within the scope of the technology
11 certification will meet the applicable stand-
12 ard;

13 “(iv) as applicable, information to
14 demonstrate that the modified procedure or
15 procedures submitted under subsection
16 (c)(2)(F) continue to conform to applicable
17 requirements under section 587K; and

18 “(v) any other information requested
19 by the Secretary.

20 “(3) CHANGES IN RESPONSE TO A PUBLIC
21 HEALTH RISK.—

22 “(A) IN GENERAL.—If the holder of a tech-
23 nology certification makes a change to an in
24 vitro clinical test or tests to address a potential
25 risk to public health by adding a new specifica-

tion or test method, such holder may immediately implement such change and shall submit a notification for such change to the Secretary within 30 days.

“(B) *CONTENT.*—Any notification to the Secretary under this paragraph shall include—

“(i) a summary of the relevant change;

“(ii) the rationale for implementing such change;

“(iii)(I) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, the modified procedures; or

“(II) if the procedures were not changed, an explanation as to why they were not changed; and

“(iv) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, data from a representative in vitro clinical test or tests that support a showing that, in using the modified procedures, all eligible in vitro clinical tests within the scope of the technology certification will meet the applicable standard.

1 “(f) *TEMPORARY HOLD.*—

2 “(1) *IN GENERAL.*—Subject to the process speci-
 3 fied in paragraph (2), and based on one or more find-
 4 ings under paragraph (4), the Secretary may issue a
 5 temporary hold prohibiting any holder of a tech-
 6 nology certification order issued under this section
 7 from introducing into interstate commerce an in vitro
 8 clinical test that was not previously the subject of a
 9 listing under section 587J. The temporary hold shall
 10 identify the grounds for the temporary hold under
 11 paragraph (4) and the rationale for such finding.

12 “(2) *PROCESS FOR ISSUING A TEMPORARY*
 13 *HOLD.*—If the Secretary makes a finding that a tem-
 14 porary hold may be warranted based on one or more
 15 grounds specified in paragraph (4), the Secretary
 16 shall promptly notify the holder of the technology cer-
 17 tification order of such finding and provide 30 cal-
 18 endar days for the developer to come into compliance
 19 with or otherwise resolve the finding.

20 “(3) *WRITTEN REQUESTS.*—Any written request
 21 to the Secretary from the holder of a technology cer-
 22 tification order that a temporary hold under para-
 23 graph (1) be removed shall receive a decision, in writ-
 24 ing and specifying the reasons therefore, within 90
 25 days after receipt of such request. Any such request

1 *shall include information to support the removal of*
2 *the temporary hold.*

3 “(4) *GROUND* *S FOR TEMPORARY HOLD.—The*
4 *Secretary may initiate a temporary hold under this*
5 *subsection upon a finding that the holder of a tech-*
6 *nology certification order—*

7 “(A) *is not in compliance with the condi-*
8 *tions of the technology certification order pursu-*
9 *ant to subsection (b)(1)(D);*

10 “(B) *offers one or more in vitro clinical*
11 *tests with advertising or labeling that is false or*
12 *misleading;*

13 “(C) *has reported a correction or removal of*
14 *an in vitro clinical test that is offered under a*
15 *technology certification order under this section*
16 *and has failed to demonstrate that the issue or*
17 *issues causing the correction or removal does not*
18 *adversely impact the ability of other in vitro*
19 *clinical tests offered under the same technology*
20 *certification order to meet the applicable stand-*
21 *ard; or*

22 “(D) *has introduced into interstate com-*
23 *merce an in vitro clinical test under a tech-*
24 *nology certification order and such test is adul-*
25 *terated or misbranded, based on a determination*

1 *by the Secretary, and has failed to demonstrate*
 2 *that the issue or issues causing the adulteration*
 3 *or misbranding does not adversely impact the*
 4 *ability of other in vitro clinical tests offered*
 5 *under the same technology certification granted*
 6 *under this section to meet the applicable stand-*
 7 *ard.*

8 “(g) *WITHDRAWAL.*—*The Secretary may, after due no-*
 9 *tice and opportunity for an informal hearing, issue an*
 10 *order withdrawing a technology certification order includ-*
 11 *ing all tests introduced into interstate commerce under the*
 12 *technology certification order if the Secretary finds that—*

13 “(1) *the application, supplement, or report*
 14 *under subsection (h) contains false or misleading in-*
 15 *formation or fails to reveal a material fact;*

16 “(2) *such holder fails to correct false or mis-*
 17 *leading labeling or advertising upon the request of the*
 18 *Secretary;*

19 “(3) *in connection with a technology certifi-*
 20 *cation, the holder provides false or misleading infor-*
 21 *mation to the Secretary; or*

22 “(4) *the holder of such technology certification*
 23 *order fails to correct the grounds for a temporary hold*
 24 *within a timeframe specified in the temporary hold*
 25 *order.*

1 “(h) *REPORTS TO CONGRESS.*—

2 “(1) *IN GENERAL.*—Not later than 1 year after
3 the effective date of the *VALID Act of 2022*, and an-
4 nually thereafter for the next 4 years, the Secretary
5 shall submit to the Committee on Health, Education,
6 Labor, and Pensions of the Senate and the Committee
7 on Energy and Commerce of the House of Representa-
8 tives, and make publicly available, including through
9 posting on the website of the Food and Drug Admin-
10 istration, a report containing the information de-
11 scribed in paragraph (2).

12 “(2) *CONTENT.*—

13 “(A) *IN GENERAL.*—Each report under
14 paragraph (1) shall address, at a minimum—

15 “(i) the total number of applications
16 for technology certifications filed, issued,
17 withdrawn, and denied;

18 “(ii) the total number of technology
19 certification orders the Secretary put on
20 temporary hold under subsection (h) and
21 the number of technology certification orders
22 withdrawn under subsection (i);

23 “(iii) the types of technologies for
24 which the Secretary issued technology cer-
25 tification orders;

1 “(iv) the total number of holders of
2 technology certification orders that are in
3 effect; and

4 “(v) the total number of in vitro clin-
5 ical test categories that required premarket
6 review under section 587B that were redes-
7 ignated as eligible in vitro clinical tests
8 under this section.

9 “(B) *FINAL REPORT*.—The fifth report sub-
10 mitted under paragraph (1) shall include a sum-
11 mary of, and responses to, comments raised in
12 the docket.

13 “(C) *PERFORMANCE REPORTS*.—The reports
14 required under this section may be issued with
15 performance reports as required under section
16 829 of the *VALID Act of 2022*.

17 “(i) *PUBLIC MEETING AND INPUT*.—

18 “(1) *PUBLIC DOCKET*.—Not later than 30 days
19 after the date of enactment of the *VALID Act of 2022*,
20 the Secretary shall establish a public docket to receive
21 comments concerning recommendations for implemen-
22 tation of this section, including criteria and proce-
23 dures for subsections (c) through (h). The public dock-
24 et shall remain open for at least 1 year after the es-
25 tablishment of the public docket.

1 “(2) *PUBLIC MEETING.*—Not later than 180 days
 2 after the date of enactment of the *VALID Act* of 2022,
 3 the Secretary shall convene a public meeting to which
 4 stakeholders from organizations representing patients
 5 and consumers, academia, and the *in vitro* clinical
 6 test industry are invited to discuss the technology cer-
 7 tification process including application requirements,
 8 inspections, alignment with third-party accreditors,
 9 and the definition of the term ‘technology’ under sec-
 10 tion 587.

11 “(j) *REGULATIONS.*—The Secretary shall issue regula-
 12 tions regarding the technology certification process, includ-
 13 ing describing criteria or procedures relating to technology
 14 certification under this section, which shall be subject to
 15 public comment for a minimum of 60 days from issuance
 16 prior to finalizing such regulations after considering the
 17 comments received. The regulation shall include an outline
 18 of the application process, opportunities to meet with offi-
 19 cials of the Food and Drug Administration, and plans to
 20 streamline inspections.

21 “(k) *NOTIFICATION.*—

22 “(1) *IN GENERAL.*—Notwithstanding subsection
 23 (a)(1), a first-of-a-kind *in vitro* clinical test or a com-
 24 bination product that meets the definition of a mod-
 25 erate-risk test under section 587A may be introduced

1 *into interstate commerce under a technology certifi-*
 2 *cation order that has been issued by the Secretary,*
 3 *subject to other applicable requirements if—*

4 *“(A) the developer provides notification to*
 5 *the Secretary 60 days prior to introducing such*
 6 *tests into interstate commerce that includes in-*
 7 *formation demonstrating that the test is mod-*
 8 *erate-risk and within the scope of the applicable*
 9 *technology certification order; and*

10 *“(B) the Secretary has not issued a notifi-*
 11 *cation to the developer under paragraph (2) be-*
 12 *fore such time has elapsed.*

13 *“(2) NOTIFICATION FROM SECRETARY.—The Sec-*
 14 *retary shall issue a notification to the developer that*
 15 *such test may not be introduced into interstate com-*
 16 *merce under such order if the Secretary determines*
 17 *that—*

18 *“(A) such test—*

19 *“(i) does not meet the definition of a*
 20 *moderate-risk test under section 587A;*

21 *“(ii) is not eligible to be introduced*
 22 *into interstate commerce under any of sub-*
 23 *paragraphs (A) through (E) of subsection*
 24 *(a)(1); or*

1 “(iii) is not eligible to be introduced
 2 into interstate commerce under the ref-
 3 erenced technology certification order issued
 4 by the Secretary because it is not within the
 5 scope of the technology certification order
 6 under subsection (b)(2); or

7 “(B) based on the information included in
 8 the notification submitted by the developer pur-
 9 suant to this subsection, there is insufficient in-
 10 formation for the Secretary to make the deter-
 11 minations described in clauses (i), (ii), and (iii)
 12 of subparagraph (A).

13 **“SEC. 587E. MITIGATING MEASURES.**

14 “(a) *ESTABLISHMENT OF MITIGATING MEASURES.—*

15 “(1) *ESTABLISHING, CHANGING, OR WITH-*
 16 *DRAWING.—*

17 “(A) *ESTABLISHMENT.—The Secretary may*
 18 *establish and require, on the basis of evidence,*
 19 *mitigating measures for any in vitro clinical test*
 20 *or category of in vitro clinical tests with the*
 21 *same indications for use that is introduced or*
 22 *delivered for introduction into interstate com-*
 23 *merce after the establishment of such mitigating*
 24 *measures.*

1 “(B) *METHODS OF ESTABLISHMENT.*—*The*
 2 *Secretary may establish mitigating measures—*

3 “*(i) under the process set forth in sub-*
 4 *paragraph (D);*

5 “*(ii) as provided under section 587F;*
 6 *or*

7 “*(iii) through a premarket approval or*
 8 *technology certification order, which may*
 9 *establish mitigating measures for an indi-*
 10 *vidual in vitro clinical test or a category of*
 11 *in vitro clinical tests.*

12 “(C) *METHODS OF CHANGE OR WITH-*
 13 *DRAWAL.*—*The Secretary may change or with-*
 14 *draw mitigating measures—*

15 “*(i) under the process set forth in sub-*
 16 *paragraph (D); or*

17 “*(ii) as provided under section 587F.*

18 “(D) *PROCESS FOR ESTABLISHMENT,*
 19 *CHANGE, OR WITHDRAWAL.*—*Notwithstanding*
 20 *subchapter II of chapter 5 of title 5, United*
 21 *States Code, the Secretary may, upon the initia-*
 22 *tive of the Secretary or upon petition of an in-*
 23 *terested person—*

24 “*(i) establish, change, or withdraw*
 25 *mitigating measures for an in vitro clinical*

1 *test or category of in vitro clinical tests*
 2 *by—*

3 “(I) *publishing a proposed order*
 4 *in the Federal Register;*

5 “(II) *providing an opportunity*
 6 *for public comment for a period of not*
 7 *less than 30 60 calendar days; and*

8 “(III) *after consideration of any*
 9 *comments submitted, publishing a final*
 10 *order in the Federal Register that re-*
 11 *sponds to the comments submitted, and*
 12 *which shall include a reasonable tran-*
 13 *sition period.*

14 “(E) *EFFECT OF MITIGATING MEASURES ON*
 15 *GRANDFATHERED TESTS.—A mitigating measure*
 16 *shall not be required by the Secretary for an in*
 17 *vitro clinical test subject to section 587G(a).*

18 “(2) *IN VITRO CLINICAL TESTS PREVIOUSLY*
 19 *CLEARED OR EXEMPT AS DEVICES WITH SPECIAL CON-*
 20 *TROLS.—*

21 “(A) *IN GENERAL.—Any special controls*
 22 *applicable to an in vitro clinical test previously*
 23 *cleared or exempt under section 510(k), or classi-*
 24 *fied under section 513(f)(2) prior to date of en-*
 25 *actment of the VALID Act of 2022, including*

1 *any such special controls established during the*
 2 *period beginning on the date of enactment of the*
 3 *VALID Act of 2022 and ending on the effective*
 4 *date of such Act (as described in section 5(b) of*
 5 *such Act)—*

6 *“(i) shall continue to apply to such in*
 7 *vitro clinical test after such effective date;*
 8 *and*

9 *“(ii) are deemed to be mitigating*
 10 *measures as of the effective date specified in*
 11 *section 825(a)(1)(A) of the VALID Act of*
 12 *2022.*

13 *“(B) CHANGES.—Notwithstanding subpara-*
 14 *graph (A), the Secretary may establish, change,*
 15 *or withdraw mitigating measures for such tests*
 16 *or category of tests using the procedures under*
 17 *paragraph (1).*

18 *“(b) DOCUMENTATION.—*

19 *“(1) IN VITRO CLINICAL TESTS SUBJECT TO PRE-*
 20 *MARKET REVIEW.—The developer of an in vitro clin-*
 21 *ical test subject to premarket review under section*
 22 *587B and to which mitigating measures apply*
 23 *shall—*

24 *“(A) in accordance with section*
 25 *587B(c)(2)(G)(i), submit documentation to the*

1 *Secretary as part of the application for the test*
2 *under subsection (c) or (d) of section 587B dem-*
3 *onstrating that such mitigating measures have*
4 *been met;*

5 *“(B) if such application is approved, main-*
6 *tain documentation demonstrating that such*
7 *mitigating measures continue to be met following*
8 *a test modification by the developer; and*

9 *“(C) make such documentation available to*
10 *the Secretary upon request or inspection.*

11 *“(2) OTHER TESTS.—The developer of an in*
12 *vitro clinical test that is offered under a technology*
13 *certification order or other exemption from premarket*
14 *review under section 587B and to which mitigating*
15 *measures apply shall—*

16 *“(A) maintain documentation in accord-*
17 *ance with the applicable quality requirements*
18 *under section 587J demonstrating that such*
19 *mitigating measures continue to be met following*
20 *a test modification by the developer;*

21 *“(B) make such documentation available to*
22 *the Secretary upon request or inspection; and*

23 *“(C) include in the performance summary*
24 *for such test a brief description of how such miti-*
25 *gating measures are met, if applicable.*

1 **“SEC. 587F. REGULATORY PATHWAY DESIGNATION.**

2 **“(a) PATHWAY DETERMINATIONS.—**

3 **“(1) IN GENERAL.—***After considering available*
 4 *evidence with respect to an in vitro clinical test or*
 5 *category of in vitro clinical tests with the same in-*
 6 *tended use, including the identification, establish-*
 7 *ment, and implementation of mitigating measures*
 8 *under section 587E, as appropriate, the Secretary*
 9 *may, upon the initiative of the Secretary or upon re-*
 10 *quest of a developer, determine that—*

11 *“(A) such in vitro clinical test is high-risk*
 12 *and subject to premarket review under section*
 13 *587B;*

14 *“(B) such in vitro clinical tests, including*
 15 *a first-of-a-kind test, is moderate-risk and subject*
 16 *to abbreviated premarket review under section*
 17 *587B(b) or technology certification under section*
 18 *587D(a)(1); or*

19 *“(C) such in vitro clinical test, including a*
 20 *first-of-a-kind test is low-risk or otherwise ex-*
 21 *empt from premarket review under section 587B.*

22 **“(2) REQUESTS.—**

23 **“(A) SUBMISSIONS BY DEVELOPERS.—**

24 **“(i) ABBREVIATED PREMARKET RE-**
 25 **VIEW; TECHNOLOGY CERTIFICATION.—***A de-*
 26 *veloper submitting a request that the Sec-*

1 retary make a determination as described
2 in paragraph (1)(B) shall submit informa-
3 tion to support that the *in vitro* clinical test
4 is moderate-risk or propose mitigating
5 measures, if applicable, that would support
6 such a determination.

7 “(ii) *LOW-RISK; EXEMPT FROM PRE-*
8 *MARKET REVIEW.*—A developer submitting
9 a request that the Secretary make a deter-
10 mination as described in paragraph (1)(C)
11 shall submit information that the *in vitro*
12 clinical test is low-risk, or otherwise appro-
13 priate for exemption from premarket review
14 under section 587B and propose mitigating
15 measures, if applicable, that would support
16 such a determination.

17 “(B) *RESPONSE BY THE SECRETARY.*—Not
18 later than 30 days after receiving a request
19 under clause (i) or (ii) of subparagraph (A), the
20 Secretary shall provide a timely response de-
21 scribing whether or not the Secretary will ini-
22 tiate the process for making a determination
23 under paragraph (1)(B) or (1)(C) as described
24 in paragraph (4).

1 “(3) *SUFFICIENCY OF MITIGATING MEASURES.*—
 2 *When determining whether mitigating measures for*
 3 *an in vitro clinical test, or category of in vitro clin-*
 4 *ical tests, are sufficient to make such test moderate-*
 5 *risk or low-risk, the Secretary shall take into account*
 6 *the following:*

7 “(A) *The degree to which the technology for*
 8 *the intended use of the in vitro clinical test is*
 9 *well-characterized, taking into consideration fac-*
 10 *tors that include one or more of the following:*

11 “(i) *Peer-reviewed literature.*

12 “(ii) *Practice guidelines.*

13 “(iii) *Consensus standards.*

14 “(iv) *Recognized standards of care.*

15 “(v) *Use of such technology, including*
 16 *historical use.*

17 “(vi) *Multiple scientific publications*
 18 *by different authors.*

19 “(vii) *Adoption by the scientific or*
 20 *clinical community.*

21 “(viii) *Real world evidence.*

22 “(B) *Whether the criteria for performance of*
 23 *the test are well-established to be sufficient for*
 24 *the intended use.*

1 “(C) *The clinical circumstances under*
2 *which the in vitro clinical test is used, including*
3 *whether the in vitro clinical test is the sole deter-*
4 *minate for the diagnosis or treatment of the tar-*
5 *geted disease, and the availability of other tests*
6 *(such as confirmatory or adjunctive tests) or rel-*
7 *evant material standards.*

8 “(D) *Whether such mitigating measures suf-*
9 *ficiently mitigate the risk of harm such that the*
10 *test or category of tests is moderate-risk or low-*
11 *risk.*

12 “(4) *PROCESS.—*

13 “(A) *IN GENERAL.—For a test that is not*
14 *first-of-a-kind, any action under paragraph (1)*
15 *shall be made by publication of a notice of such*
16 *proposed action on the website of the Food and*
17 *Drug Administration, the consideration of com-*
18 *ments to a public docket on such proposal, and*
19 *publication of a final action on such website*
20 *within 60 calendar days of the close of the com-*
21 *ment period posted to such public docket, not-*
22 *withstanding subchapter II of chapter 5 of title*
23 *5, United States Code.*

1 “(B) PROCESS FOR FIRST-OF-A-KIND
2 TEST.—*In the case of an in vitro clinical test*
3 *that is first-of-a-kind, the process is as follows:*

4 “(i) *Any determination that the test is*
5 *subject to premarket approval or abbrevi-*
6 *ated premarket review under subpara-*
7 *graph (A) or (B) of paragraph (1) shall be*
8 *published on the website of the Food and*
9 *Drug Administration, notwithstanding sub-*
10 *clause II of chapter 5 of title 5, United*
11 *States Code, only after the in vitro clinical*
12 *test is approved under section 587B. Until*
13 *that time, the determination shall not be*
14 *binding on other in vitro clinical tests.*

15 “(ii) *Any determination other than*
16 *those made under clause (i) shall be made*
17 *by publication of a notice of final action on*
18 *the website of the Food and Drug Adminis-*
19 *tration, notwithstanding subchapter II of*
20 *chapter 5 of title 5, United States Code.*

21 “(5) NO EFFECT ON GRANDFATHERING DETER-
22 MINATIONS.—*A determination under paragraph (1)*
23 *shall have no effect on the applicability of section*
24 *587G to an in vitro clinical tests.*

1 “(b) *TRANSITION PERIOD.*—Upon a decision by the
 2 Secretary to change a regulatory pathway designation, or
 3 reclassifies an *in vitro* clinical test, or category of *in vitro*
 4 clinical tests, the Secretary shall provide an appropriate
 5 transition period with respect to any new requirements.

6 “(c) *APPEALS.*—A decision by the Secretary under this
 7 section shall be deemed a significant decision subject to ap-
 8 peal under section 587P.

9 “(d) *ADVISORY COMMITTEE.*—The Secretary may re-
 10 quest recommendations from an advisory committee under
 11 section 587H pursuant to carrying out this section.

12 “(e) *REQUEST FOR INFORMAL FEEDBACK.*—Before
 13 submitting a premarket application or technology certifi-
 14 cation application for an *in vitro* clinical test—

15 “(1) the developer of the test may submit to the
 16 Secretary a written request for a meeting, conference,
 17 or written feedback to discuss and provide informa-
 18 tion relating to the regulation of such *in vitro* clinical
 19 test which may include—

20 “(A) the submission process and the type
 21 and amount of evidence expected to demonstrate
 22 the applicable standard;

23 “(B) which regulatory pathway is appro-
 24 priate for an *in vitro* clinical test; and

1 “(C) *an investigation plan for an in vitro*
 2 *clinical test, including a clinical protocol; and*

3 “(2) *upon receipt of such a request, the Secretary*
 4 *shall—*

5 “(A) *if a meeting is requested—*

6 “(i) *within 60 calendar days after such*
 7 *receipt, or within such time period as may*
 8 *be agreed to by the developer, meet or confer*
 9 *with the developer submitting the request;*
 10 *and*

11 “(ii) *within 15 calendar days after*
 12 *such meeting or conference, provide to the*
 13 *developer a written record or response de-*
 14 *scribing the issues discussed and conclusions*
 15 *reached in the meeting or conference; and*

16 “(B) *if written feedback is requested, pro-*
 17 *vide feedback to the requestor within 75 days*
 18 *after such receipt.*

19 **“SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.**

20 “(a) *IN GENERAL.—Subject to subsection (d), an in*
 21 *vitro clinical test is exempt from the requirements of this*
 22 *subchapter specified in subsection (b) if—*

23 “(1) *the test was first offered for clinical use,*
 24 *and was not intended solely for investigational use,*

1 *before the date of enactment of the VALID Act of*
2 *2022;*

3 *“(2) the test was developed by a clinical labora-*
4 *tory for which a certificate was in effect under section*
5 *353 of the Public Health Service Act that meets the*
6 *requirements for performing tests of high complexity;*

7 *“(3) the test is performed—*

8 *“(A) in the same clinical laboratory in*
9 *which the test was developed for which a certifi-*
10 *cation is still in effect under section 353 of the*
11 *Public Health Service Act that meets the require-*
12 *ments to perform tests of high complexity;*

13 *“(B) by another clinical laboratory for*
14 *which a certificate is in effect under section 353*
15 *of such Act that meets the requirements to per-*
16 *form tests of high complexity, and that is within*
17 *the same corporate organization and having*
18 *common ownership by the same parent corpora-*
19 *tion as the laboratory in which the test was de-*
20 *veloped; or*

21 *“(C) in the case of a test that was developed*
22 *by the Centers for Disease Control and Preven-*
23 *tion or another laboratory in a public health lab-*
24 *oratory network coordinated or managed by the*
25 *Centers for Disease Control and Prevention, by*

1 *a clinical laboratory for which a certificate is in*
2 *effect under section 353 of such Act that meets*
3 *the requirements to perform tests of high com-*
4 *plexity, and that is within a public health lab-*
5 *oratory network coordinated or managed by the*
6 *Centers for Disease Control and Prevention;*

7 *“(4) the test does not have in effect an approval*
8 *under section 515, a clearance under section 510(k),*
9 *an authorization under section 513(f)(2), or an ex-*
10 *emption under section 520(m), or licensure under sec-*
11 *tion 351 of the Public Health Service Act;*

12 *“(5) any modification to the test on or after the*
13 *date of enactment of the VALID Act of 2022 is made*
14 *by the initial developer, conforms with section*
15 *587C(a)(6)(A)(ii), and does not meet the criteria in*
16 *subsection (d)(1);*

17 *“(6) when used as an investigational in vitro*
18 *clinical test, such test complies with section 587S, as*
19 *applicable;*

20 *“(7) the test is offered with an order from an au-*
21 *thorized person as required under section 353 of the*
22 *Public Health Service Act, and was offered with a*
23 *prescription required under section 809.30(f) of title*
24 *21, Code of Federal Regulations prior to the effective*
25 *date of this subchapter;*

1 “(8) the test is not for use with home specimen
2 collection, unless the specimen is collected with a col-
3 lection container, receptacle, or kit that—

4 “(A) has been approved, cleared, or author-
5 ized by the Secretary for home specimen collec-
6 tion and the collection is performed pursuant to
7 the approved, cleared, or authorized labeling, in-
8 cluding any indication for use as prescription
9 use or over-the-counter use, or

10 “(B) is exempt from premarket review and
11 its use is consistent with applicable limitations
12 on the exemption;

13 “(9) the test is not a specimen receptacle or in-
14 strument;

15 “(10) each test report for the test bears a state-
16 ment that reads as follows: ‘This in vitro clinical test
17 was introduced into commerce prior to the applica-
18 tion of the VALID Act and is exempt from FDA pre-
19 market review.’; and

20 “(11) the developer of the test—

21 “(A) maintains documentation dem-
22 onstrating that the test meets and continues to
23 meet the criteria set forth in this subsection; and

24 “(B) makes such documentation available to
25 the Secretary upon request.

1 “(b) *EXEMPTIONS APPLICABLE TO GRANDFATHERED*
 2 *TESTS.*—*An in vitro clinical test that meets the criteria*
 3 *specified in subsection (a) is exempt from premarket review*
 4 *under 587B, labeling requirements under 587L, and test de-*
 5 *sign requirements and quality requirements under 587K,*
 6 *and may be lawfully offered subject to the other applicable*
 7 *requirements of this Act.*

8 “(c) *MODIFICATIONS.*—*In the case of an in vitro clin-*
 9 *ical test that meets the criteria specified in subsection (a),*
 10 *such test continues to qualify for the exemptions described*
 11 *in subsection (b) if the test is modified and the modification*
 12 *is of a type described in subsection (a)(5), and the person*
 13 *modifying such in vitro clinical test—*

14 “(1) *documents each such modification and*
 15 *maintains documentation of the basis for such deter-*
 16 *mination;*

17 “(2) *provides such documentation relating to the*
 18 *change to the Secretary upon request or inspection;*
 19 *and*

20 “(3) *does not modify the in vitro clinical test*
 21 *such that it no longer meets the criteria under sub-*
 22 *section (a).*

23 “(d) *REQUEST FOR INFORMATION.*—

24 “(1) *CRITERIA.*—*The criteria described in this*
 25 *paragraph are any of the following:*

1 “(A) *There is a lack of valid scientific evi-*
 2 *dence to support that the in vitro clinical test is*
 3 *analytically valid or clinically valid.*

4 “(B) *Such in vitro clinical test is being of-*
 5 *fered by its developer with any false or mis-*
 6 *leading analytical or clinical claims.*

7 “(C) *It is probable that such in vitro clin-*
 8 *ical test will cause serious adverse health con-*
 9 *sequences.*

10 “(2) *PROCESS.—*

11 “(A) *WRITTEN REQUEST FOR INFORMA-*
 12 *TION.—The Secretary may issue a written re-*
 13 *quest to a developer identifying specific scientific*
 14 *concerns, based on credible information, with an*
 15 *in vitro clinical test, which indicate that one or*
 16 *more of the criteria described in paragraph (1)*
 17 *apply to such in vitro clinical test. Such written*
 18 *request shall include specific information re-*
 19 *quests pertaining to such criteria.*

20 “(B) *DEADLINE FOR SUBMITTING INFORMA-*
 21 *TION.—Not later than 45 days after receiving a*
 22 *request for information under subparagraph*
 23 *(A)—*

24 “(i) *the developer of an in vitro clin-*
 25 *ical test—*

1 “(I) may seek a teleconference
2 prior to the submission of information
3 under subclause (II) to discuss the Sec-
4 retary’s request; and

5 “(II) shall submit the information
6 requested pursuant to subparagraph
7 (A), and may include in such submis-
8 sion a request for a teleconference; and
9 “(ii) the Secretary shall—

10 “(I) schedule a teleconference re-
11 quested under clause (i)(I); and

12 “(II) hold a teleconference if re-
13 quested within 10 days of the Sec-
14 retary’s receipt of the information sub-
15 mitted under clause (i)(II).

16 “(C) REVIEW DEADLINE.—Upon receiving a
17 submission under subparagraph (B), the Sec-
18 retary shall—

19 “(i) review the submitted information
20 within 45 calendar days of such receipt,
21 which may include communication with the
22 developer; and

23 “(ii) determine whether the criteria
24 listed in paragraph (1) apply to the in
25 vitro clinical test and communicate such de-

1 *termination to the developer as described in*
2 *subparagraph (D).*

3 “(D) *COMMUNICATION AND RESULTS OF DE-*
4 *TERMINATION.—The Secretary shall notify the*
5 *developer, in writing, of the Secretary’s deter-*
6 *mination under subparagraph (C), as follows:*

7 “(i) *If the Secretary determines that*
8 *none of the criteria listed in paragraph (1)*
9 *apply to the in vitro clinical test, such test*
10 *shall be exempt from relevant requirements*
11 *of this subchapter, as set forth in subsection*
12 *(b), subject to applicable limitation.*

13 “(ii) *If the Secretary determines that*
14 *one or more of the criteria listed in sub-*
15 *paragraph (1) apply to the test but such a*
16 *determination may be resolved within a*
17 *reasonable time, and the test has not been*
18 *previously subject to this subsection on the*
19 *basis of the same or substantially similar*
20 *scientific concerns identified in the written*
21 *request issued under paragraph (d)(2)(A)—*

22 “(I) *the Secretary shall notify the*
23 *developer of such a determination and*
24 *allow the developer to seek a teleconfer-*
25 *ence to discuss the finding;*

1 “(II) the developer shall submit
2 information demonstrating resolution
3 of the determination within 15 days of
4 receiving the notification; and

5 “(III) the Secretary shall make a
6 determination within 30 days of the
7 submission of information as to wheth-
8 er the criteria under paragraph (1)
9 apply to the test.

10 “(iii) If the Secretary determines that
11 none of the criteria listed in paragraph (1)
12 apply to the test, such test shall be exempt
13 from relevant requirements of the sub-
14 chapter as set forth in subsection (b), subject
15 to applicable limitations.

16 “(iv) If the Secretary determines that
17 one or more of the criteria listed in para-
18 graph (1) apply to the *in vitro* clinical test,
19 such test is not exempt as set forth in this
20 section and shall not be offered unless ap-
21 proved under section 587B, or, upon a de-
22 termination by the Secretary pursuant to
23 section 587F, offered under a technology
24 certification order under section 587D or of-
25 fered as a low-risk test.

1 “(v) *If the Secretary determines that*
 2 *one or more of the criteria listed in para-*
 3 *graph (1) apply to the in vitro clinical test*
 4 *and clause (ii) does not apply, the in vitro*
 5 *clinical test is not exempt as set forth in*
 6 *section and shall not be offered unless ap-*
 7 *proved under section 587B, or upon a deter-*
 8 *mination by the Secretary pursuant to sec-*
 9 *tion 587F, offered under a technology cer-*
 10 *tification order under section 587D or of-*
 11 *fered as a low-risk test.*

12 **“SEC. 587H. ADVISORY COMMITTEES.**

13 “(a) *IN GENERAL.—The Secretary may establish advi-*
 14 *sory committees or use advisory committee panels of experts*
 15 *established before the date of enactment of the VALID Act*
 16 *of 2022 (including a device classification panel under sec-*
 17 *tion 513) for the purposes of providing expert scientific ad-*
 18 *vice and making recommendations related to—*

19 “(1) *the approval of an application for an in*
 20 *vitro clinical test submitted under this subchapter, in-*
 21 *cluding for evaluating, as applicable, the analytical*
 22 *validity, clinical validity, and safety of in vitro clin-*
 23 *ical tests;*

24 “(2) *the potential effectiveness of mitigating*
 25 *measures for a determination of the applicable regu-*

1 *latory pathway under section 587F(b) or risk evalua-*
 2 *tion for an in vitro clinical test or tests;*

3 *“(3) quality requirements under section 587K or*
 4 *applying such requirements to in vitro clinical tests*
 5 *developed or imported by developers;*

6 *“(4) appeals under section 587P; or*

7 *“(5) such other purposes as the Secretary deter-*
 8 *mines appropriate.*

9 *“(b) APPOINTMENTS.—*

10 *“(1) VOTING MEMBERS.—The Secretary shall ap-*
 11 *point to each committee established under subsection*
 12 *(a), as voting members, individuals who are qualified*
 13 *by training and experience to evaluate in vitro clin-*
 14 *ical tests referred to the committee for the purposes*
 15 *specified in subsection (a), including individuals*
 16 *with, to the extent feasible, scientific expertise in the*
 17 *development of such in vitro clinical tests, laboratory*
 18 *operations, and the use of in vitro clinical tests. The*
 19 *Secretary shall designate one member of each com-*
 20 *mittee to serve as chair.*

21 *“(2) NONVOTING MEMBERS.—In addition to the*
 22 *individuals appointed pursuant to paragraph (1), the*
 23 *Secretary shall appoint to each committee established*
 24 *under subsection (a), as nonvoting members—*

1 “(A) a representative of consumer interests;
2 and

3 “(B) a representative of interests of in vitro
4 clinical test developers not directly affected by
5 the matter to be brought before the committee.

6 “(3) *LIMITATION.*—No individual who is a reg-
7 ular full-time employee of the United States and en-
8 gaged in the administration of this Act may be a
9 member of any advisory committee established under
10 subsection (a).

11 “(4) *EDUCATION AND TRAINING.*—The Secretary
12 shall, as appropriate, provide education and training
13 to each new committee member before such member
14 participates in a committee’s activities, including
15 education regarding requirements under this Act and
16 related regulations of the Secretary, and the adminis-
17 trative processes and procedures related to committee
18 meetings.

19 “(5) *MEETINGS.*—The Secretary shall ensure
20 that scientific advisory committees meet regularly
21 and at appropriate intervals so that any matter to be
22 reviewed by such a committee can be presented to the
23 committee not more than 60 calendar days after the
24 matter is ready for such review. Meetings of the com-

1 *mittee may be held using electronic or telephonic com-*
 2 *munication to convene the meetings.*

3 “(6) *COMPENSATION.—Members of an advisory*
 4 *committee established under subsection (a), while at-*
 5 *tending meetings or conferences or otherwise engaged*
 6 *in the business of the advisory committee—*

7 “(A) *shall be entitled to receive compensa-*
 8 *tion at rates to be fixed by the Secretary, but not*
 9 *to exceed the daily equivalent of the rate in effect*
 10 *for positions classified above level GS–15 of the*
 11 *General Schedule; and*

12 “(B) *may be allowed travel expenses as au-*
 13 *thorized by section 5703 of title 5, United States*
 14 *Code, for employees serving intermittently in the*
 15 *Government service.*

16 “(c) *GUIDANCE.—The Secretary may issue guidance*
 17 *on the policies and procedures governing advisory commit-*
 18 *tees established under subsection (a).*

19 **“SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

20 “(a) *IN GENERAL.—The purpose of this section is to*
 21 *encourage the Secretary, and provide the Secretary with*
 22 *sufficient authority, to apply efficient and flexible ap-*
 23 *proaches to expedite the development of, and prioritize the*
 24 *review of, in vitro clinical tests that represent breakthrough*
 25 *technologies.*

1 “(b) *ESTABLISHMENT OF PROGRAM.*—*The Secretary*
2 *shall establish a program to expedite the development of,*
3 *and provide for the priority review of, in vitro clinical tests.*

4 “(c) *ELIGIBILITY.*—*The program developed under sub-*
5 *section (b) shall be available for any in vitro clinical test*
6 *that—*

7 “(1) *provides or enables more effective treatment*
8 *or diagnosis of life-threatening or irreversibly debili-*
9 *tating human disease or conditions compared to exist-*
10 *ing approved or cleared in vitro clinical tests, includ-*
11 *ing an in vitro clinical test offered under a technology*
12 *certification order; and*

13 “(2) *is a test—*

14 “(A) *that represents a breakthrough tech-*
15 *nology;*

16 “(B) *for which no approved or cleared alter-*
17 *native in vitro clinical test exists, including no*
18 *in vitro clinical test offered under a technology*
19 *certification order;*

20 “(C) *that offers a clinically meaningful ad-*
21 *vantage over existing alternative in vitro clinical*
22 *tests that are approved or cleared (including in*
23 *vitro clinical tests offered under a technology cer-*
24 *tification order), including the potential to re-*
25 *duce or eliminate the need for hospitalization,*

1 *improve patient quality of life, facilitate pa-*
 2 *tients' ability to manage their own care (such as*
 3 *through self-directed personal assistance), or es-*
 4 *tablish long-term clinical efficiencies; or*

5 *“(D) the availability of which is in the best*
 6 *interest of patients or public health.*

7 *“(d) DESIGNATION.—*

8 *“(1) REQUEST.—To receive breakthrough des-*
 9 *ignation under this section, an applicant may request*
 10 *that the Secretary designate the in vitro clinical test*
 11 *for expedited development and priority review. Any*
 12 *such request for designation may be made at any*
 13 *time prior to, or at the time of, the submission of an*
 14 *application under section 587B or 587D, and shall*
 15 *include information demonstrating that the test meets*
 16 *the criteria described in subsection (c).*

17 *“(2) DETERMINATION.—Not later than 60 cal-*
 18 *endar days after the receipt of a request under para-*
 19 *graph (1), the Secretary shall determine whether the*
 20 *in vitro clinical test that is the subject of the request*
 21 *meets the criteria described in subsection (c). If the*
 22 *Secretary determines that the test meets the criteria,*
 23 *the Secretary shall designate the test for expedited de-*
 24 *velopment and priority review.*

1 “(3) *REVIEW.*—*Review of a request under para-*
 2 *graph (1) shall be undertaken by a team that is com-*
 3 *posed of experienced staff and senior managers of the*
 4 *Food and Drug Administration.*

5 “(4) *WITHDRAWAL.*—

6 “(A) *IN GENERAL.*—*The designation of an*
 7 *in vitro clinical test under this subsection is*
 8 *deemed to be withdrawn, and such in vitro clin-*
 9 *ical test shall no longer be eligible for designa-*
 10 *tion under this section, if an application for ap-*
 11 *proval for such test under section 587B or 587D*
 12 *is denied. Such test shall be eligible for break-*
 13 *through designation upon a new request for such*
 14 *designation.*

15 “(B) *EXCEPTION.*—*The Secretary may not*
 16 *withdraw a designation granted under this sub-*
 17 *section based on the subsequent approval or tech-*
 18 *nology certification of another in vitro clinical*
 19 *test that—*

20 “(i) *is designated under this section; or*

21 “(ii) *was given priority review under*
 22 *section 515B.*

23 “(e) *ACTIONS.*—*For purposes of expediting the devel-*
 24 *opment and review of in vitro clinical tests under this sec-*
 25 *tion, the Secretary may take the actions and additional ac-*

1 tions set forth in paragraphs (1) and (2), respectively, of
 2 section 515B(e) when reviewing such tests. Any reference
 3 or authorization in section 515B(e) with respect to a device
 4 shall be deemed a reference or authorization with respect
 5 to an in vitro clinical test for purposes of this section.

6 “(f) *GUIDANCE*.—Not later than the date specified for
 7 final guidance under section 825 of the *VALID Act* of 2022,
 8 the Secretary shall issue final guidance on the implementa-
 9 tion of this section. Such guidance shall—

10 “(1) set forth the process by which a person may
 11 seek a designation under subsection (d);

12 “(2) provide a template for request under sub-
 13 section (d);

14 “(3) identify the criteria the Secretary will use
 15 in evaluating a request for designation; and

16 “(4) identify the criteria and processes the Sec-
 17 retary will use to assign a team of staff, including
 18 team leaders, to review in vitro clinical tests des-
 19 ignated for expedited development and priority re-
 20 view, including any training required for such per-
 21 sonnel to ensure effective and efficient review.

22 “(g) *RULES OF CONSTRUCTION*.—Nothing in this sec-
 23 tion shall be construed to affect—

24 “(1) the criteria and standards for evaluating an
 25 application pursuant to section 587B or 587D, in-

cluding the recognition of valid scientific evidence as described in section 587(20) and consideration and application of the least burdensome means described under section 587AA(c);

“(2) the authority of the Secretary with respect to clinical holds under section 587S;

“(3) the authority of the Secretary to act on an application pursuant to section 587B before completion of an establishment inspection, as the Secretary determines appropriate; or

“(4) the authority of the Secretary with respect to postmarket surveillance under section 587X.

“SEC. 587J. REGISTRATION AND LISTING.

“(a) REGISTRATION REQUIREMENT.—

“(1) IN GENERAL.—Each person described in subsection (b)(1) shall—

“(A) during the period beginning on October 1 and ending on December 31 of each year, register with the Secretary the name of such person, places of business of such person, all establishments engaged in the activities specified under this paragraph, the establishment registration number of each such establishment, and a point of contact for each such establishment, including an electronic point of contact; and

1 “(B) submit an initial registration con-
2 taining the information required under subpara-
3 graph (A) not later than—

4 “(i) the effective date of this section if
5 such establishment is engaged in any activ-
6 ity described in subsection (b)(1) on such ef-
7 fective date, unless the Secretary establishes
8 by guidance a date later than such imple-
9 mentation date for all or a category of such
10 establishments; or

11 “(ii) 30 days prior to engaging in any
12 activity described in subsection (b)(1), if
13 such establishment is not engaged in any
14 activity described in this paragraph on such
15 effective date.

16 “(2) *REGISTRATION NUMBERS.*—The Secretary
17 may assign a registration number to any person or
18 an establishment registration number to any estab-
19 lishment registered in accordance with this section.
20 Registration information shall be made publicly
21 available by publication on the website maintained by
22 the Food and Drug Administration, in accordance
23 with subsection (d).

24 “(3) *INSPECTION.*—Each person or establishment
25 that is required to be registered with the Secretary

1 *under this section shall be subject to inspection pursu-*
 2 *ant to section 704.*

3 *“(b) LISTING INFORMATION FOR IN VITRO CLINICAL*
 4 *TESTS.—*

5 *“(1) IN GENERAL.—Each person who—*

6 *“(A) is a developer; and*

7 *“(B) introduces or proposes to begin the in-*
 8 *troduction or delivery for introduction into*
 9 *interstate commerce through an exemption under*
 10 *subsection (a)(1), (a)(2), (a)(3), or (g) of section*
 11 *587C or section 587G or through the filing of an*
 12 *application under section 587B or section 587D,*
 13 *shall submit a listing to the Secretary containing the*
 14 *information described in paragraph (2), (4), or (5),*
 15 *as applicable, in accordance with the applicable*
 16 *schedule described under subsection (c). Such listing*
 17 *shall be prepared in such form and manner as the*
 18 *Secretary may specify in guidance. Listing informa-*
 19 *tion shall be submitted through the comprehensive test*
 20 *information system in accordance with section 587T,*
 21 *as appropriate.*

22 *“(2) SUBMISSIONS.—Each developer submitting*
 23 *a listing under paragraph (1) shall electronically sub-*
 24 *mit to the comprehensive test information system de-*
 25 *scribed in section 587T the following information, as*

1 *applicable, for each in vitro clinical test for which*
2 *such person is a developer in the form and manner*
3 *prescribed by the Secretary, taking into account the*
4 *least burdensome requirements under section*
5 *587AA(c):*

6 *“(A) Name of the establishment and its es-*
7 *tablishment registration number.*

8 *“(B) Contact information for the official*
9 *correspondent for the listing.*

10 *“(C) Name (common name and trade name,*
11 *if applicable) of the in vitro clinical test and its*
12 *test listing number (when available).*

13 *“(D) The certificate number for any labora-*
14 *tory certified by the Secretary under section 353*
15 *of the Public Health Service Act that meets the*
16 *requirements to perform high-complexity testing*
17 *and that is the developer of the in vitro clinical*
18 *test, and the certificate number under such sec-*
19 *tion for any laboratory that is performing the*
20 *test, is within the same corporate organization,*
21 *and has common ownership by the same parent*
22 *corporation.*

23 *“(E) Whether the in vitro clinical test is, as*
24 *applicable, offered as a test approved under sec-*
25 *tion 587B, cleared to be offered under a granted*

1 *technology certification order, or offered as an*
2 *exempt in vitro clinical test under section 587C*
3 *of 587G.*

4 *“(F) Indications for use information under*
5 *section 587(10).*

6 *“(G) A brief summary of the analytical and*
7 *clinical performance of the in vitro clinical test,*
8 *and as applicable, the lot release criteria.*

9 *“(H) A brief description of conformance*
10 *with any applicable mitigating measures, re-*
11 *strictions, and standards.*

12 *“(I) Representative labeling for the in vitro*
13 *clinical test, as appropriate.*

14 *“(3) TEST LISTING NUMBER.—The Secretary*
15 *may assign a test listing number to each in vitro*
16 *clinical test that is the subject of a listing under this*
17 *section. The process for assigning test listing numbers*
18 *may be established through guidance, and may in-*
19 *clude the recognition of standards, formats, or conven-*
20 *tions developed by a third-party organization.*

21 *“(4) ABBREVIATED LISTING.—A person who is*
22 *not a developer but is otherwise required to register*
23 *pursuant to subsection (a) shall submit an abbrev-*
24 *viated listing to the Secretary containing the infor-*
25 *mation described in subparagraphs (A) through (C) of*

1 paragraph (2), and the name of the developer. The in-
2 formation shall be submitted in accordance with the
3 applicable schedule described under subsection (c).
4 Such abbreviated listing shall be prepared in such
5 form and manner as the Secretary may specify
6 through guidance. Listing information shall be sub-
7 mitted to the comprehensive test information system
8 in accordance with section 587T, as appropriate.

9 “(5) *GRANDFATHERED TESTS.*—A developer of
10 fering a test that is a grandfathered in vitro clinical
11 test under section 587G(a) shall submit listing infor-
12 mation required under subparagraphs (A) through
13 (F) of paragraph (2), and may submit a statement of
14 the performance specifications for such in vitro clin-
15 ical tests.

16 “(6) *EXEMPT TESTS.*—A developer of an in vitro
17 clinical test who introduces or proposes to begin the
18 introduction or delivery for introduction into inter-
19 state commerce that is otherwise exempt from the re-
20 quirement to submit listing information pursuant to
21 an exemption under section 587C may submit listing
22 information under this subsection.

23 “(c) *TIMELINES FOR SUBMISSION OF LISTING INFOR-*
24 *MATION.*—

1 “(1) *IN GENERAL.*—*The timelines for submission*
2 *of registration and listing under subsections (a) and*
3 *(b) are as follows:*

4 “(A) *For an in vitro clinical test that was*
5 *listed as a device under section 510(j) prior to*
6 *the effective date of this section, a person shall*
7 *maintain a device listing under section 510 until*
8 *such time as the system for submitting the listing*
9 *information required under subsection (b) be-*
10 *comes available and thereafter shall submit the*
11 *listing information not later than the later of 1*
12 *year after the system for submitting the listing*
13 *under this section becomes available or the effec-*
14 *tive date of this section.*

15 “(B) *For an in vitro clinical test that is*
16 *subject to grandfathering under section 587G(a)*
17 *a person shall submit the listing information re-*
18 *quired under subsection (b)(5) not later than the*
19 *later of 1 year after the system for submitting*
20 *the listing under this section becomes available*
21 *or the effective date of this section.*

22 “(C) *For an in vitro clinical test that is not*
23 *described in subparagraph (A) or (B), a person*
24 *shall submit the required listing information as*
25 *follows:*

1 “(i) *For an in vitro clinical test that*
2 *is not exempt from premarket approval*
3 *under section 587B, a person shall submit*
4 *the required listing information, prior to of-*
5 *fering the in vitro clinical test and not later*
6 *than 30 business days after the date of ap-*
7 *proval of the premarket approval applica-*
8 *tion.*

9 “(ii) *For an in vitro clinical test that*
10 *is exempt from premarket review under sec-*
11 *tion 587C, the required listing information*
12 *shall be submitted prior to offering the in*
13 *vitro clinical test.*

14 “(2) *UPDATES.—*

15 “(A) *UPDATES AFTER CHANGES.—Each de-*
16 *veloper required to submit listing information*
17 *under this section shall update such information*
18 *within 10 business days of any change that*
19 *causes any previously listed information to be*
20 *inaccurate or incomplete.*

21 “(B) *ANNUAL UPDATES.—Each developer*
22 *required to submit listing information under this*
23 *section shall update its information annually*
24 *during the period beginning on October 1 and*
25 *ending on December 31 of each year.*

1 “(d) *PUBLIC AVAILABILITY OF LISTING INFORMA-*
2 *TION.*—

3 “(1) *IN GENERAL.*—*Listing information sub-*
4 *mitted pursuant to this section shall be made publicly*
5 *available on the website of the Food and Drug Ad-*
6 *ministration in accordance with paragraph (3).*

7 “(2) *CONFIDENTIALITY.*—*Listing information for*
8 *an in vitro clinical test that is subject to premarket*
9 *approval or technology certification shall remain con-*
10 *fidential until such date as the in vitro clinical test*
11 *receives the applicable premarket approval or the de-*
12 *veloper receives a technology certification order and*
13 *for subsequent tests introduced under a technology*
14 *certification order until their introduction.*

15 “(3) *EXCEPTIONS FROM PUBLIC AVAILABILITY*
16 *REQUIREMENTS.*—*The public listing requirements of*
17 *this subsection shall not apply to any registration*
18 *and listing information submitted under subsection*
19 *(a) or (b), if the Secretary determines that such infor-*
20 *mation—*

21 “(A) *is a trade secret or confidential com-*
22 *mercial or financial information; or*

23 “(B) *if posted, would present a risk to na-*
24 *tional security.*

1 “(e) *SUBMISSION OF INFORMATION BY ACCREDITED*
 2 *PERSONS.*—*If agreed upon by the developer, the informa-*
 3 *tion required under this section may be submitted by a per-*
 4 *son accredited under section 587Q.*

5 **“SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.**

6 “(a) *APPLICABILITY.*—

7 “(1) *IN GENERAL.*—*Each developer and each*
 8 *other person required to register under section*
 9 *587J(b)(1) shall establish and maintain quality re-*
 10 *quirements in accordance with the applicable require-*
 11 *ments set forth in subsection (b).*

12 “(2) *CERTIFIED LABORATORY REQUIREMENTS.*—
 13 *A developer shall establish and maintain quality re-*
 14 *quirement under subsection (b)(2) or (b)(3), as appli-*
 15 *cable, if such developer is a clinical laboratory cer-*
 16 *tified by the Secretary under section 353 of the Public*
 17 *Health Service Act that—*

18 “(A) *is certified to perform high-complexity*
 19 *testing;*

20 “(B) *develops an in vitro clinical test that*
 21 *is for use only—*

22 “(i) *within the laboratory certified by*
 23 *the Secretary under such section 353 in*
 24 *which such test was developed; or*

1 “(ii) *within another laboratory cer-*
2 *tified by the Secretary under such section*
3 *353 if such laboratory is—*

4 “(I) *within the same corporate or-*
5 *ganization and has common ownership*
6 *by the same parent corporation as the*
7 *laboratory in which the test was devel-*
8 *oped; or*

9 “(II) *within a public health lab-*
10 *oratory network coordinated or man-*
11 *aged by the Centers for Disease Control*
12 *and Prevention, if the test is developed*
13 *by a public health laboratory or the*
14 *Centers for Disease Control and Pre-*
15 *vention; and*

16 “(C) *does not manufacture, produce, or dis-*
17 *tribute in vitro clinical tests other than labora-*
18 *tory test protocols.*

19 “(3) *REGULATIONS.—The Secretary shall pro-*
20 *mulgate quality system regulations implementing this*
21 *section. In promulgating such regulations under this*
22 *section, the Secretary shall consider whether, and to*
23 *what extent, international harmonization is appro-*
24 *priate.*

1 “(4) *QUALITY SYSTEMS FOR HYBRID DEVEL-*
 2 *OPERS OF BOTH LABORATORY TEST PROTOCOLS AND*
 3 *OTHER IN VITRO CLINICAL TESTS.*—*An entity that de-*
 4 *velops both finished products and laboratory test pro-*
 5 *ocols and other in vitro clinical tests shall comply*
 6 *with subsection (b)(1) for activities related to the de-*
 7 *velopment of any in vitro clinical test that is not a*
 8 *laboratory test protocol and with subsection (b)(2) or*
 9 *(b)(3), as applicable, for activities related to the devel-*
 10 *opment of any laboratory test protocol.*

11 “(b) *QUALITY REQUIREMENTS.*—

12 “(1) *IN GENERAL.*—*The quality requirements*
 13 *applicable under this section shall—*

14 “(A) *avoid duplication of regulations and*
 15 *guidance under section 353 of the Public Health*
 16 *Service Act;*

17 “(B) *not apply to laboratory operations;*
 18 *and*

19 “(C) *include the following, as applicable,*
 20 *subject to subparagraphs (A) and (B) and para-*
 21 *graphs (2) and (3)—*

22 “(i) *management responsibilities;*

23 “(ii) *quality audits;*

24 “(iii) *personnel;*

25 “(iv) *design controls;*

- 1 “(v) document controls;
- 2 “(vi) purchasing controls;
- 3 “(vii) identification and traceability;
- 4 “(viii) production and process controls;
- 5 “(ix) acceptance activities;
- 6 “(x) nonconforming in vitro clinical
- 7 tests;
- 8 “(xi) corrective and preventive action;
- 9 “(xii) labeling and packaging controls;
- 10 “(xiii) handling, storage, distribution,
- 11 and installation;
- 12 “(xiv) complaints and records;
- 13 “(xv) servicing; and
- 14 “(xvi) statistical techniques.

15 “(2) *EXCEPTION FOR LABORATORY TEST PROTO-*
 16 *COLS.—Developers that are developing test protocols*
 17 *for use as described in subsection (a)(2)(B)(i) are ex-*
 18 *empt from the requirements under paragraph (1)(C)*
 19 *except for the requirements described in clauses (iv),*
 20 *(ix), (xi), and (xiv) of such paragraph.*

21 “(3) *QUALITY REQUIREMENTS FOR CERTAIN LAB-*
 22 *ORATORIES DISTRIBUTING LABORATORY TEST PROTO-*
 23 *COLS WITHIN ORGANIZATIONS OR PUBLIC HEALTH*
 24 *NETWORKS.—Quality requirements applicable to the*
 25 *developer who is distributing a laboratory test pro-*

1 *tocol as described in subsection (a)(2)(B)(ii) shall*
 2 *consist of the following:*

3 “(A) *Clauses (iv), (ix), (xi), (xiv), (xii) of*
 4 *paragraph (1)(B).*

5 “(B) *The requirement to maintain records*
 6 *of the laboratories to which the laboratory test*
 7 *protocol is distributed.*

8 “(c) *REGULATIONS.—In implementing quality re-*
 9 *quirements for test developers that participate in inter-*
 10 *national audit programs under this section, the Secretary*
 11 *shall—*

12 “(1) *for purposes of facilitating international*
 13 *harmonization, consider whether the developer par-*
 14 *ticipates in an international audit program in which*
 15 *the United States participates and recognizes compli-*
 16 *ance with, or conformance to, such standards recog-*
 17 *nized by the Secretary; and*

18 “(2) *ensure a least burdensome approach de-*
 19 *scribed in section 587AA(c) by leveraging, to the ex-*
 20 *tent applicable, the quality assurance requirements*
 21 *applicable to developers certified by the Secretary*
 22 *under section 353 of the Public Health Service Act.*

23 **“SEC. 587L. LABELING REQUIREMENTS.**

24 “(a) *IN GENERAL.—An in vitro clinical test shall bear*
 25 *or be accompanied by labeling, as applicable, that meets*

1 *the requirements set forth in subsections (b) and (c), unless*
 2 *such test is exempt under subsection (d) or (e).*

3 “(b) *LABELS.*—

4 “(1) *IN GENERAL.*—*The label of an in vitro clin-*
 5 *ical test, shall meet the requirements set forth in*
 6 *paragraph (2) if there is an immediate container to*
 7 *which the label is applied.*

8 “(2) *REGULATIONS.*—*The label of an in vitro*
 9 *clinical test shall state the name and place of business*
 10 *of its developer and meet the requirements set forth in*
 11 *regulations promulgated in accordance with this sec-*
 12 *tion.*

13 “(c) *LABELING.*—

14 “(1) *IN GENERAL.*—*Labeling of an in vitro clin-*
 15 *ical test, including labeling in the form of a package*
 16 *insert, website, standalone laboratory reference docu-*
 17 *ment, or other similar document shall include—*

18 “(A) *adequate directions for use and shall*
 19 *meet the requirements set forth in regulations*
 20 *promulgated under this section, except as pro-*
 21 *vided in subsection (d) or (e); and*

22 “(B) *the information described in para-*
 23 *graph (2), as applicable.*

24 “(2) *CONTENT.*—*Labeling of an in vitro clinical*
 25 *test shall include—*

1 “(A) the test listing number that was pro-
2 vided to the developer at the time of listing;

3 “(B) information to facilitate reporting an
4 adverse event;

5 “(C) information regarding accessing the
6 performance summary data displayed in the list-
7 ing database for the test;

8 “(D) the indications for use of the in vitro
9 clinical test; and

10 “(E) any warnings, contraindications, or
11 limitations.

12 “(3) PUBLIC AVAILABILITY OF INFORMATION.—
13 The Secretary shall make all of the information de-
14 scribed in paragraph (2) with respect to each in vitro
15 clinical test available to the public, as applicable, in
16 accordance with section 587T, except to the extent
17 that the Secretary determines that such informa-
18 tion—

19 “(A) is trade secret or confidential commer-
20 cial or financial information; or

21 “(B) if posted, could compromise national
22 security.

23 “(4) ADDITIONAL REQUIREMENTS.—Labeling for
24 an in vitro clinical test used for immunohematology
25 testing shall meet the applicable requirements set

1 *forth in part 660 of title 21, Code of Federal Regula-*
 2 *tions (or any successor regulations), related to the la-*
 3 *beling of blood grouping reagents, reagent red blood*
 4 *cells, and anti-human globulin.*

5 “(d) *EXEMPTIONS AND ALTERNATIVE REQUIRE-*
 6 *MENTS.—*

7 “(1) *IN GENERAL.—*

8 “(A) *IN GENERAL.—With respect to an in*
 9 *vitro clinical test that meets the criteria of sub-*
 10 *paragraph (B), the ‘state in one place’ regula-*
 11 *tions under section 809.10(b) of title 21, Code of*
 12 *Federal Regulations (or any successor regula-*
 13 *tions) may be satisfied by the laboratory posting*
 14 *such information on its website or in multiple*
 15 *documents, if such documents are maintained*
 16 *and accessible in one place.*

17 “(B) *APPLICABLE TESTS.—An in vitro clin-*
 18 *ical test meets the criteria of this subparagraph*
 19 *if such test is—*

20 “(i) *developed by a laboratory certified*
 21 *by the Secretary under section 353 of the*
 22 *Public Health Service Act that meets the re-*
 23 *quirements to perform tests of high-com-*
 24 *plexity; and*

25 “(ii) *performed in—*

1 “(I) the same laboratory in which
2 such test was developed; or

3 “(II) by another laboratory cer-
4 tified by the Secretary under section
5 353 of the Public Health Service Act
6 that—

7 “(aa) meets the requirements
8 to perform tests of high com-
9 plexity; and

10 “(bb) is under common own-
11 ership and control as the labora-
12 tory that developed the test.

13 “(2) *TEST INSTRUMENT LABELING.*—Unless the
14 instrument is the entire test system, the labeling for
15 an instrument is not required to bear the information
16 indicated in paragraphs (3), (4), (5), (7), (8), (9),
17 (10), (11), (12), and (13) of section 809.10(b) of title
18 21, Code of Federal Regulations (or any successor reg-
19 ulations).

20 “(3) *REAGENT LABELING.*—For purposes of com-
21 pliance with subsection (c)(1), the labeling for a rea-
22 gent intended for use as a replacement in an in vitro
23 clinical test may be limited to that information nec-
24 essary to identify the reagent adequately and to de-
25 scribe its proper use in the test.

1 “(4) *INVESTIGATIONAL USE.*—A shipment or
2 other delivery of an *in vitro* clinical test for investiga-
3 tional use pursuant to section 587S shall be exempt
4 from the labeling requirements of subsections (b) and
5 (c)(1) and from any standard promulgated through
6 regulations, except as required under section 353 of
7 the Public Health Service Act or section 587R of this
8 Act.

9 “(5) *GENERAL PURPOSE LABORATORY RE-*
10 *AGENTS.*—The labeling of general purpose laboratory
11 reagents (such as hydrochloric acid) whose uses are
12 generally known by persons trained in their use need
13 not bear the directions for use required by subsection
14 (c)(1)(A).

15 “(6) *OVER-THE-COUNTER TEST SPECIMEN RE-*
16 *CEPTACLE LABELING.*—The labeling for over-the-
17 counter test specimen receptacles for drugs of abuse
18 testing shall bear the name and place of business of
19 the developer included in the registration under sec-
20 tion 587J and any information specified in applica-
21 ble regulations promulgated under this section, in
22 language appropriate for the intended users.

23 “(e) *TESTS IN THE STRATEGIC NATIONAL STOCK-*
24 *PILE.*—

1 “(1) *IN GENERAL.*—*The Secretary may grant an*
 2 *exception or alternative to any provision listed in this*
 3 *section, unless explicitly required by a statutory pro-*
 4 *vision outside this subchapter, for specified lots,*
 5 *batches, or other units of an in vitro clinical test, if*
 6 *the Secretary determines that compliance with such*
 7 *labeling requirement could adversely affect the avail-*
 8 *ability of such products that are, or will be, included*
 9 *in the Strategic National Stockpile under section*
 10 *319F–2 of the Public Health Service Act.*

11 “(2) *REGULATIONS.*—*The Secretary may issue*
 12 *regulations amending section 809.11 of title 21, Code*
 13 *of Federal Regulations (or any successor regulation)*
 14 *to apply in full or in part to in vitro clinical tests*
 15 *and in vitro clinical test developers.*

16 “(f) *REGULATIONS.*—*The Secretary shall issue or re-*
 17 *visé regulations related to standardized, general content and*
 18 *format for in vitro clinical test labeling pursuant to this*
 19 *subsection.*

20 **“SEC. 587M. ADVERSE EVENT REPORTING.**

21 “(a) *IN GENERAL.*—*Each in vitro clinical test devel-*
 22 *oper shall establish and maintain a system for establishing*
 23 *and maintaining records of adverse events and reporting*
 24 *adverse events in accordance with this section.*

1 “(b) *SUBMISSION OF INDIVIDUAL REPORTS.*—A devel-
 2 oper shall submit an individual adverse event not later than
 3 5 calendar days after the developer receives or becomes
 4 aware of an adverse event that reasonably suggests that an
 5 *in vitro* clinical test may—

6 “(1) have caused or contributed to a patient or
 7 user death; or

8 “(2) present an imminent threat to public
 9 health.

10 “(c) *SUBMISSION OF QUARTERLY REPORTS.*—As ap-
 11 plicable, a developer shall submit quarterly reports that in-
 12 clude any *in vitro* clinical test errors and serious injuries
 13 that occurred during the applicable quarter. Such quarterly
 14 reports shall be submitted not later than the end of the quar-
 15 ter following the quarter in which the developer receives or
 16 becomes aware of such adverse events.

17 “(d) *DEFINITIONS.*—For the purposes of this section—

18 “(1) the term ‘*in vitro* clinical test error’ means
 19 a failure of an *in vitro* clinical test to meet its per-
 20 formance specifications, or to otherwise perform as
 21 intended by the developer, including an inaccurate re-
 22 sult resulting from such failure; and

23 “(2) the term ‘serious injury’ means—

24 “(A) a significant delay in a diagnosis that
 25 results in the absence, delay, or discontinuation

1 *of critical medical treatment or that irreversibly*
 2 *or seriously and negatively alters the course of a*
 3 *disease or condition; or*

4 “(B) *an injury that—*

5 “(i) *is life threatening;*

6 “(ii) *results in permanent impairment*
 7 *of a body function or permanent damage to*
 8 *a body structure; or*

9 “(iii) *necessitates medical or surgical*
 10 *intervention to preclude permanent impair-*
 11 *ment of a body function or permanent dam-*
 12 *age to a body structure.*

13 “(e) *REGULATIONS.—The Secretary shall promulgate*
 14 *regulations to implement this section.*

15 **“SEC. 587N. CORRECTIONS AND REMOVALS.**

16 “(a) *REGULATIONS.—The Secretary shall promulgate*
 17 *regulations, or amend existing regulations, as appropriate,*
 18 *to implement this section.*

19 “(b) *REPORTS OF CORRECTIONS AND REMOVALS.—*

20 “(1) *IN GENERAL.—Each in vitro clinical test*
 21 *developer shall report to the Secretary any correction*
 22 *or removal of an in vitro clinical test undertaken by*
 23 *such developer if the correction or removal was under-*
 24 *taken—*

1 “(A) to reduce the risk to health posed by
2 the *in vitro* clinical test; or

3 “(B) to remedy a violation of this Act
4 caused by the *in vitro* clinical test which may
5 present a risk to health.

6 “(2) *EXCEPTION FOR IN VITRO CLINICAL TESTS*
7 *OFFERED UNDER A TECHNOLOGY CERTIFICATION*
8 *ORDER.*—For any eligible test offered under a tech-
9 nology certification order under section 587D, a cor-
10 rection and removal report for any correction or re-
11 moval of an *in vitro* clinical test should demonstrate
12 that the issue or issues causing the correction or re-
13 moval do not adversely impact the ability of other *in*
14 vitro clinical tests offered under the same technology
15 certification order to meet the applicable standard.

16 “(c) *TIMING.*—A developer shall submit any report re-
17 quired under this subsection to the Secretary within 15
18 business days of initiating such correction or removal.

19 “(d) *RECORDKEEPING.*—A developer of an *in vitro*
20 clinical test that undertakes a correction or removal of an
21 *in vitro* clinical test which is not required to be reported
22 under this subsection shall keep a record of such correction
23 or removal.

24 “(e) *RECALL COMMUNICATIONS.*—Upon the reporting
25 of a correction or removal by the developer—

1 “(1) the Secretary shall classify such correction
2 or removal under this section within 45 calendar
3 days; and

4 “(2) not later than 70 calendar days after the
5 developer or other responsible party notifies the Sec-
6 retary that it has completed a recall action, the Sec-
7 retary shall provide the developer or other responsible
8 party with a written statement closing the recall ac-
9 tion or stating the reasons the Secretary cannot close
10 the recall at that time.

11 **“SEC. 587O. RESTRICTED IN VITRO CLINICAL TESTS.**

12 “(a) *APPLICABILITY.*—

13 “(1) *IN GENERAL.*—For the types of in vitro
14 clinical tests described in paragraph (3), the Sec-
15 retary may require, in issuing an approval of an in
16 vitro clinical test under section 587B, granting a
17 technology certification order under section 587D, or
18 in issuing a determination under section 587F(a), or
19 by issuing a regulation, that such test, or category of
20 tests, be restricted to sale, distribution, or use upon
21 such conditions as the Secretary may prescribe under
22 paragraph (2).

23 “(2) *CONDITIONS.*— The Secretary may pre-
24 scribe conditions under this section, based on avail-
25 able evidence, with respect to an in vitro clinical test

1 described in paragraph (3), that are determined to be
 2 needed due to the potential for harmful effect of such
 3 test (including any resulting absence, significant
 4 delay, or discontinuation of appropriate medical
 5 treatment), and are necessary to ensure that the test
 6 meets the applicable standard.

7 “(3) *IN VITRO CLINICAL TESTS SUBJECT TO RE-*
 8 *STRICTIONS.*—The restrictions or conditions author-
 9 ized under this section may be applied by the Sec-
 10 retary to any high-risk or moderate-risk in vitro clin-
 11 ical test, prescription home-use in vitro clinical test,
 12 direct-to-consumer in vitro clinical test, or over-the-
 13 counter in vitro clinical test.

14 “(b) *LABELING AND ADVERTISING OF A RESTRICTED*
 15 *IN VITRO CLINICAL TEST.*—The labeling and advertising
 16 of an in vitro clinical test to which restrictions apply under
 17 subsection (a) shall bear such appropriate statements of the
 18 restrictions as the Secretary may prescribe in an approval
 19 under section 587B, an order under section 587D, a deter-
 20 mination under section 587F(a), or in regulation, as appli-
 21 cable.

22 “(c) *DEVICE RESTRICTIONS.*—An in vitro clinical test
 23 that was offered as a restricted device prior to the date of
 24 enactment of this subchapter—

1 “(1) shall continue to comply with the applicable
2 restrictions under section 515 or section 520(e) until
3 this subchapter takes effect; and

4 “(2) except for in vitro clinical tests required to
5 meet the requirements of section 809.30 of title 21,
6 Code of Federal Regulations prior to the effective date
7 of this subchapter specified in section 825(a)(1)(A) of
8 the VALID Act of 2022, such restrictions described in
9 paragraph (1) shall be deemed to be restrictions under
10 this subchapter as of such effective date.

11 **“SEC. 587P. APPEALS.**

12 “(a) SIGNIFICANT DECISION.—

13 “(1) IN GENERAL.—The Secretary shall—

14 “(A) maintain a substantive summary of
15 the scientific and regulatory rationale for any
16 significant decision of the Food and Drug Ad-
17 ministration pursuant to section 587F, regard-
18 ing—

19 “(i) the submission of an application
20 for, or a review of, an in vitro clinical test
21 under section 587B or section 587D;

22 “(ii) an exemption under section 587C;

23 or

1 “(iii) any requirements for mitigation
 2 measures to an in vitro clinical test or cat-
 3 egory of in vitro clinical tests; and

4 “(B) include in such summaries documenta-
 5 tion of significant controversies or differences of
 6 opinion and the resolution of such controversies
 7 or differences of opinion.

8 “(2) *PROVISION OF DOCUMENTATION.*—Upon re-
 9 quest, the Secretary shall furnish a substantive sum-
 10 mary described in paragraph (1) to the person who
 11 has made, or is seeking to make, a submission de-
 12 scribed in such paragraph.

13 “(3) *APPLICATION OF LEAST BURDENSOME RE-*
 14 *QUIREMENTS.*—The substantive summary required
 15 under this subsection shall include a brief statement
 16 regarding how the least burdensome requirements
 17 were considered and applied consistent with section
 18 587AA(c), as applicable.

19 “(b) *REVIEW OF SIGNIFICANT DECISIONS.*—

20 “(1) *REQUEST FOR SUPERVISORY REVIEW OF*
 21 *SIGNIFICANT DECISION.*—A developer may request a
 22 supervisory review of the significant decision de-
 23 scribed in subsection (a)(1). Such review may be con-
 24 ducted at the next supervisory level or higher above
 25 the agency official who made the significant decision.

1 “(2) *SUBMISSION OF REQUEST.*—A developer re-
2 *questing a supervisory review under paragraph (1)*
3 *shall submit such request to the Secretary not later*
4 *than 30 days after the decision for which the review*
5 *is requested and shall indicate in the request whether*
6 *such developer seeks an in-person meeting or a tele-*
7 *conference review.*

8 “(3) *TIMEFRAME.*—The Secretary shall schedule
9 *an in-person or teleconference review, if so requested,*
10 *not later than 30 days after such request is made. The*
11 *Secretary shall issue a decision to the developer re-*
12 *questing a review under this subsection not later than*
13 *45 days after the request is made under paragraph*
14 *(1), or, in the case of a developer who requests an in-*
15 *person meeting or teleconference, 30 days after such*
16 *meeting or teleconference.*

17 “(c) *ADVISORY PANELS.*—The process established
18 *under subsection (a) shall permit the appellant to request*
19 *review by an advisory committee established under section*
20 *587G when there is a dispute involving substantial sci-*
21 *entific fact. If an advisory panel meeting is held, the Sec-*
22 *retary shall make a determination under this subsection not*
23 *later than 45 days after the requested advisory committee*
24 *meeting has concluded.*

1 “(d) *LEAST BURDENSOME REVIEW.*—Any developer
 2 who has submitted an application under section 587B or
 3 587D may request a supervisory review of a request for ad-
 4 ditional information during an evaluation of such submis-
 5 sion within 60 calendar days of receipt of the additional
 6 information request from the Secretary.

7 “(e) *AVAILABILITY OF ALL REMEDIES.*—The proce-
 8 dures set forth in this section shall be in addition to, and
 9 not in lieu of, other remedies available to the developer.

10 **“SEC. 587Q. ACCREDITED PERSONS.**

11 “(a) *IN GENERAL.*—

12 “(1) *AUTHORIZATION.*—Beginning on the date of
 13 enactment of the *VALID Act of 2022*, the Secretary
 14 shall accredit persons for any of the following pur-
 15 poses:

16 “(A) *Reviewing applications for premarket*
 17 *approval under section 587B and making find-*
 18 *ings with respect to such applications.*

19 “(B) *Reviewing applications for technology*
 20 *certification under section 587D and making*
 21 *recommendations to the Secretary with respect to*
 22 *such applications.*

23 “(C) *Conducting inspections as specified in*
 24 *subsection (c) of in vitro clinical test developers*

1 *and other persons required to register pursuant*
 2 *to section 587J.*

3 “(2) *PERSONS SUBMITTING APPLICATIONS.*—A
 4 *person submitting an application for premarket ap-*
 5 *proval under section 587B or an application for tech-*
 6 *nology certification under section 587D may submit*
 7 *such application to the Secretary or to a person ac-*
 8 *credited pursuant to subparagraph (A) or (B) of*
 9 *paragraph (1).*

10 “(b) *ACCREDITED PERSONS APPLICATION REVIEWS,*
 11 *FINDINGS AND RECOMMENDATIONS.*—

12 “(1) *REQUIREMENTS FOR PREMARKET APPLICA-*
 13 *TION.*—

14 “(A) *REVIEW AND FINDING REQUIRE-*
 15 *MENTS.*—An accredited person receiving an ap-
 16 *plication for premarket approval under section*
 17 *587B shall either—*

18 “(i) *provide to the Secretary, together*
 19 *with the application for premarket approval*
 20 *submitted by the applicant, a finding that*
 21 *the criteria for approval of the application*
 22 *under section 587B(e)(2)(A) are met and*
 23 *issue a copy of such finding to the appli-*
 24 *cant, which finding shall plainly state—*

1 “(I) the basis for the accredited
2 person’s finding that the criteria under
3 section 587B(e)(2)(A) are met; and

4 “(II) any proposed restrictions,
5 mitigating measures, or conditions of
6 approval under section 587B(e)(2)(B),
7 as applicable; or

8 “(ii) provide a notification to the ap-
9 plicant that the accredited person cannot
10 find that the criteria for approval of the ap-
11 plication under section 587B(e)(2)(A) are
12 met and the reasons for such decision.

13 “(B) REQUESTING MISSING OR CLARIFYING
14 INFORMATION.—After receipt of an application
15 from a developer under this section, the Sec-
16 retary may request missing or clarifying infor-
17 mation from the applicant concerning the appli-
18 cation, which the developer shall promptly pro-
19 vide.

20 “(C) SECRETARY ACTION ON FINDING THAT
21 APPROVAL CRITERIA ARE MET.—If the accredited
22 person transmits a finding to the Secretary
23 under subparagraph (A)(i), then prior to the
24 date that is 45 calendar days after the trans-
25 mittal date, the Secretary shall—

1 “(i) approve the application for pre-
 2 market approval under section 587B(e)(2)
 3 with appropriate restrictions, mitigating
 4 measures, or conditions of approval, as ap-
 5 plicable; or

6 “(ii) deny approval of the application
 7 by issuing a written notice that reflects ap-
 8 propriate management input and concur-
 9 rence to the accredited person and the ap-
 10 plicant detailing the scientific basis for the
 11 Secretary’s determination that the criteria
 12 for issuance of an approval under section
 13 587B(e)(2)(A) have not been met.

14 “(D) *EFFECT OF INACTION ON FINDING.*—If
 15 the Secretary fails to take an action under sub-
 16 paragraph (C) the Secretary shall—

17 “(i) within 45 calendar days after the
 18 transmittal date, provide written feedback
 19 to the applicant that—

20 “(I) includes all outstanding
 21 issues with the application preventing
 22 the Secretary from taking an action
 23 under subparagraph (B);

24 “(II) reflects appropriate manage-
 25 ment input and concurrence; and

1 “(III) includes action items for
 2 the Secretary, the applicant, or both,
 3 as appropriate, with an estimated date
 4 of completion for the Secretary and the
 5 applicant to complete their respective
 6 tasks, as applicable; and

7 “(ii) promptly schedule a meeting or
 8 teleconference to discuss the feedback pro-
 9 vided under clause (i), unless the Secretary
 10 and applicant agree that the outstanding
 11 issues are adequately presented through
 12 written correspondence and a meeting or
 13 teleconference is not necessary.

14 “(2) REQUIREMENTS FOR TECHNOLOGY CERTIFI-
 15 CATION.—

16 “(A) REVIEW AND RECOMMENDATION RE-
 17 QUIREMENTS.—An accredited person receiving
 18 an application for technology certification under
 19 section 587D shall either—

20 “(i) provide to the Secretary, together
 21 with the application for technology certifi-
 22 cation submitted by the applicant, a rec-
 23 ommendation that the criteria for issuance
 24 of a technology certification order under
 25 section 587D(d)(3) are met and issue a

1 *copy of such recommendation to the appli-*
 2 *cant, which recommendation shall plainly*
 3 *state the basis for the accredited person's*
 4 *recommendation that the criteria under sec-*
 5 *tion 587D(d)(3) are met; or*

6 “(ii) *provide a notification to the ap-*
 7 *plicant that the accredited person cannot*
 8 *recommend that the criteria for issuance of*
 9 *a technology certification order under sec-*
 10 *tion 587D(d)(3) are met and the reasons for*
 11 *such decision.*

12 “(B) *REQUESTING MISSING OR CLARIFYING*
 13 *INFORMATION.—After receipt of an application*
 14 *under this section, the accredited person may re-*
 15 *quest missing or clarifying information from the*
 16 *applicant concerning the application, which the*
 17 *applicant shall promptly provide.*

18 “(C) *SECRETARY ACTION ON RECOMMENDA-*
 19 *TION FOR ISSUANCE OF A TECHNOLOGY CERTIFI-*
 20 *CATION ORDER.—If the accredited person trans-*
 21 *mits a recommendation to the Secretary under*
 22 *clause (i) of subparagraph (A), then prior to the*
 23 *date that is 60 calendar days after the trans-*
 24 *mittal date the Secretary shall—*

1 “(i) issue the technology certification
 2 order under section 587D(d)(3), consistent
 3 with such recommendation from the accred-
 4 ited person; or

5 “(ii) deny approval of the application
 6 by issuing a written notice to the accredited
 7 person and the applicant detailing the sci-
 8 entific basis for a determination by the Sec-
 9 retary that the criteria for issuance of a
 10 technology certification order under section
 11 587D(d)(3) have not been met.

12 “(c) *REQUIREMENTS FOR INSPECTIONS.*—

13 “(1) *IN GENERAL.*—When conducting inspection,
 14 persons accredited under subsection (a)(1)(B) shall
 15 record in writing their specific observations and shall
 16 present their observations to the designated represent-
 17 ative of the inspected establishment.

18 “(2) *INSPECTION REPORT REQUIREMENTS.*—
 19 Each person accredited under subsection (a)(1)(C)
 20 shall prepare and submit to the Secretary an inspec-
 21 tion report in a form and manner designated by the
 22 Secretary for conducting inspections. Any statement
 23 or representation made by an employee or agent of an
 24 establishment to a person accredited to conduct in-

1 *spections under subsection (a)(1)(C) shall be subject to*
 2 *section 1001 of title 18, United States Code.*

3 “(3) *SAVINGS CLAUSE.*—*Nothing in this section*
 4 *affects the authority of the Secretary to inspect any*
 5 *in vitro clinical test developer or other person reg-*
 6 *istered under section 587J or recognize inspections*
 7 *conducted by auditing organizations as described*
 8 *under section 704(g)(15).*

9 “(4) *INSPECTION LIMITATIONS.*—*The Secretary*
 10 *shall ensure that inspections carried out under this*
 11 *section are not duplicative of inspections carried out*
 12 *under section 353 of the Public Health Service Act.*
 13 *Inspections under this section shall be limited to the*
 14 *data and information necessary—*

15 “(A) *for routine surveillance activities of fa-*
 16 *cilities associated with an approved application*
 17 *under section 587B or issuance of a technology*
 18 *certification order under section 587D; or*

19 “(B) *to meet the requirements for premarket*
 20 *approval under section 587B or issuance of a*
 21 *technology certification order under section*
 22 *587D, as applicable.*

23 “(d) *ACCREDITATION.*—

24 “(1) *ACCREDITATION PROGRAM.*—*The Secretary*
 25 *may provide for accreditation under this section*

1 *through programs administered by the Food and*
 2 *Drug Administration, by other non-Federal govern-*
 3 *ment agencies, or by qualified nongovernmental orga-*
 4 *nizations. A person may be accredited for the review*
 5 *of applications submitted under sections 587B as de-*
 6 *scribed in subsection (a)(1)(A), for the review of ap-*
 7 *plications submitted under section 587D as described*
 8 *in subsection (a)(1)(B), and to conduct inspection ac-*
 9 *tivities under subsection (a)(1)(C), or for a subset of*
 10 *such reviews or activities.*

11 *“(2) ELIGIBLE PERSONS.—*

12 *“(A) MINIMUM QUALIFICATIONS.—An ac-*
 13 *credited person, at a minimum, shall—*

14 *“(i) not be an employee of the Federal*
 15 *Government;*

16 *“(ii) not engage in the activities of a*
 17 *developer, as defined in section 587(7);*

18 *“(iii) not be a person required to reg-*
 19 *ister under section 587J, unless such person*
 20 *has established sufficient processes and pro-*
 21 *ocols to separate activities to develop in*
 22 *vitro clinical tests and the activities for*
 23 *which such person would be accredited*
 24 *under subsection (a) and discloses applica-*
 25 *ble information under this section;*

1 “(iv) not be owned or controlled by,
2 and shall have no organizational, material,
3 or financial affiliation with, an in vitro
4 clinical test developer or other person re-
5 quired to register under section 587J;

6 “(v) be a legally constituted entity per-
7 mitted to conduct the activities for which it
8 seeks accreditation;

9 “(vi) ensure that the operations of such
10 person are in accordance with generally ac-
11 cepted professional and ethical business
12 practices; and

13 “(vii) include in its request for accred-
14 itation a commitment to, at the time of ac-
15 creditation and at any time it is per-
16 forming activities pursuant to this sec-
17 tion—

18 “(I) certify that the information
19 reported to the Secretary accurately re-
20 flects the data or protocol reviewed,
21 and the documented inspection find-
22 ings, as applicable;

23 “(II) limit work to that for which
24 competence and capacity are available;

1 “(III) treat information received
2 or learned, records, reports, and rec-
3 ommendations as proprietary informa-
4 tion of the person submitting such in-
5 formation; and

6 “(IV) in conducting the activities
7 for which the person is accredited in
8 respect to a particular *in vitro* clinical
9 test, protect against the use of any em-
10 ployee or consultant who has a finan-
11 cial conflict of interest regarding that
12 *in vitro* clinical test.

13 “(B) *WAIVER.*—The Secretary may waive
14 any requirements in clauses (i), (ii), (iii), or (iv)
15 of subparagraph (A) upon making a determina-
16 tion that such person has implemented other ap-
17 propriate controls sufficient to ensure a com-
18 petent and impartial review.

19 “(3) *ACCREDITATION PROCESS.*—

20 “(A) *ACCREDITATION PROCESS GUIDANCE*
21 *AND REGULATIONS.*—Not later than 180 days
22 after the date of enactment of the *VALID Act* of
23 2022, the Secretary shall issue draft guidance
24 specifying the process for submitting a request
25 for accreditation and reaccreditation under this

1 *section, including the form and content of infor-*
 2 *mation to be submitted, including the criteria*
 3 *that the Secretary will consider to accredit or*
 4 *deny accreditation and, not later than 1 year*
 5 *after the close of the comment period for the draft*
 6 *guidance, issue final guidance.*

7 *“(B) RESPONSE TO REQUEST.—The Sec-*
 8 *retary shall respond to a request for accredita-*
 9 *tion or reaccreditation within 60 calendar days*
 10 *of the receipt of the request. The Secretary’s re-*
 11 *sponse may be to accredit or reaccredit the per-*
 12 *son, to deny accreditation, or to request addi-*
 13 *tional information in support of the request. If*
 14 *the Secretary requests additional information,*
 15 *the Secretary shall respond within 60 calendar*
 16 *days of receipt of such additional information to*
 17 *accredit or deny the accreditation.*

18 *“(C) TYPE OF ACCREDITATION.—The ac-*
 19 *creditation or reaccreditation of a person shall*
 20 *specify the particular activity or activities under*
 21 *subsection (a) for which such person is accred-*
 22 *ited, and shall include any limitation to certain*
 23 *eligible in vitro clinical tests.*

24 *“(D) PUBLIC LIST.—The Secretary shall*
 25 *publish on the website of the Food and Drug Ad-*

1 *ministration a list of persons who are accredited*
2 *under this section. Such list shall be updated on*
3 *at least a monthly basis. The list shall specify*
4 *the particular activity or activities under this*
5 *section for which the person is accredited.*

6 *“(E) AUDIT.—The Secretary may audit the*
7 *performance of persons accredited under this sec-*
8 *tion for purposes of ensuring that such persons*
9 *continue to meet the published criteria for ac-*
10 *creditation, and may modify the scope or par-*
11 *ticular activities for which a person is accredited*
12 *if the Secretary determines that such person fails*
13 *to meet one or more criteria for accreditation.*

14 *“(F) SUSPENSION OR WITHDRAWAL.—The*
15 *Secretary may suspend or withdraw accredita-*
16 *tion of any person accredited under this section,*
17 *after providing notice and an opportunity for an*
18 *informal hearing, when such person is substan-*
19 *tially not in compliance with the requirements of*
20 *this section or the published criteria for accredi-*
21 *tation, or poses a threat to public health, or fails*
22 *to act in a manner that is consistent with the*
23 *purposes of this section.*

24 *“(G) REACCREDITATION.—Accredited per-*
25 *sons may be initially accredited for up to 3*

1 *years. After expiration of such initial period,*
 2 *persons may be recredited for unlimited addi-*
 3 *tional 5-year periods, as determined by the Sec-*
 4 *retary.*

5 “(e) *COMPENSATION OF ACCREDITED PERSONS.—*
 6 *Compensation of an accredited person shall be determined*
 7 *by agreement between the accredited person and the person*
 8 *who engages the services of the accredited person, and shall*
 9 *be paid by the person who engages such services.*

10 “(f) *INTERNATIONAL HARMONIZATION.—Notwith-*
 11 *standing any other provision of this section, to facilitate*
 12 *international harmonization the Secretary may recognize*
 13 *persons accredited or recognized by governments, who have*
 14 *also entered into information sharing agreements, including*
 15 *confidentiality commitments, with the Commissioner of*
 16 *Food and Drugs.*

17 “(g) *INFORMATION SHARING AGREEMENTS.—An ac-*
 18 *credited person may enter into an agreement with a test*
 19 *developer to provide information to the comprehensive test*
 20 *information system under section 587T, including any re-*
 21 *quirements under section 587J.*

22 “(h) *REPORTS.—Not later than 2 years after the effec-*
 23 *tive date of the VALID Act of 2022, and annually thereafter*
 24 *for the next 4 years, the Secretary shall post on the website*
 25 *of the Food and Drug Administration, a report describing*

1 *the Secretary's performance in implementing this section,*
2 *including the Secretary's progress in minimizing dupli-*
3 *cative reviews of applications for which an accredited person*
4 *finds the criteria for approval are met. Such reports shall*
5 *include, for each period—*

6 “(1) *with regard to premarket approval applica-*
7 *tions—*

8 “(A) *the total number of findings trans-*
9 *mitted to the Secretary under subsection*
10 *(b)(1)(A)(i);*

11 “(B) *the total number of determinations*
12 *made by the Secretary under subsection*
13 *(b)(1)(B)(i) within 30 calendar days of the*
14 *transmittal date to approve an application;*

15 “(C) *the total number of determinations*
16 *made by the Secretary under subsection*
17 *(b)(1)(B)(ii) within 30 calendar days of the*
18 *transmittal date to deny approval of an applica-*
19 *tion; and*

20 “(D) *the total number of applications that*
21 *were approved and the total number of applica-*
22 *tions that were denied approval, after the Sec-*
23 *retary failed to make a determination within 30*
24 *calendar days of the transmittal date under sub-*
25 *section (b)(1)(B); and*

1 “(2) with regard to applications for technology
2 certification—

3 “(A) the total number of recommendations
4 transmitted to the Secretary under subsection
5 (b)(2)(A)(i);

6 “(B) the total number of determinations
7 made by the Secretary under subsection
8 (b)(2)(B)(i) to issue a technology certification
9 order, including determinations made within 30
10 days of the transmittal date;

11 “(C) the total number of determinations
12 made by the Secretary under subsection
13 (b)(2)(B)(ii) to deny the application for tech-
14 nology certification, including determinations
15 made within 30 calendar days of the transmittal
16 date; and

17 “(D) the total number of technology certifi-
18 cation orders issued, and the total number of ap-
19 plications for technology certification that were
20 denied, including applications denied after the
21 Secretary failed to make a determination within
22 30 calendar days of the transmittal date under
23 subsection (b)(2)(B).

1 **“SEC. 587R. RECOGNIZED STANDARDS.**

2 “(a) *IN GENERAL.*—The Secretary may recognize all
 3 or part of appropriate standards established by nationally
 4 or internationally recognized standards development orga-
 5 nizations for which a person may submit a declaration of
 6 conformity in order to meet a requirement under this sub-
 7 chapter to which that standard is applicable. Standards for
 8 in vitro diagnostic devices previously recognized under sec-
 9 tion 514(c) shall be considered recognized standards under
 10 this section. Recognized and proposed standards shall be ac-
 11 cessible to the public at no charge. The application of any
 12 such consensus standard shall only apply prospectively. The
 13 Secretary shall issue regulations establishing the criteria
 14 and process, for such recognition and adoption.

15 “(b) *AMENDMENT PROCESS.*—The procedures estab-
 16 lished in this section or in regulation or guidance issued
 17 under this section shall apply to amendment of an existing
 18 standard.

19 **“SEC. 587S. INVESTIGATIONAL USE.**

20 “(a) *IN GENERAL.*—Subject to the conditions pre-
 21 scribed in subsections (c), (d), (e), (f), and (g), an in vitro
 22 clinical test for investigational use shall be exempt from the
 23 requirements of this subchapter, other than sections 587A,
 24 587P, 587T, and 587V. The Secretary may amend parts
 25 50, 54, and 56 of title 21 of the Code of Federal Regulations
 26 to apply to in vitro clinical tests to permit the investiga-

1 *tional use of such tests by experts qualified by scientific*
 2 *training and experience.*

3 “(b) *REGULATIONS.*—

4 “(1) *IN GENERAL.*—Not later than 2 years after
 5 the date of enactment of the *VALID Act of 2022*, the
 6 Secretary shall promulgate regulations, or amend ex-
 7 isting regulations, to implement this section.

8 “(2) *VARIATION.*—The requirements in the regu-
 9 lations promulgated under this section shall take into
 10 account variations based on—

11 “(A) *the scope and duration of clinical test-*
 12 *ing to be conducted under investigation that is*
 13 *the subject of such application;*

14 “(B) *the number of human subjects that are*
 15 *to be involved in such testing;*

16 “(C) *the need to permit changes to be made*
 17 *to the in vitro clinical test involved during test-*
 18 *ing conducted in accordance with a plan re-*
 19 *quired under subsection (c)(6); or*

20 “(D) *whether the clinical testing of such in*
 21 *vitro clinical test is for the purpose of developing*
 22 *data to obtain approval to offer such test.*

23 “(c) *APPLICATION FOR INVESTIGATIONAL USE.*—The
 24 following shall apply with respect to *in vitro clinical tests*
 25 *for investigational use:*

1 “(1) *SIGNIFICANT RISK AND OTHER STUDIES.*—

2 *In the case of an in vitro clinical test the investiga-*
 3 *tional use of which poses a significant risk to the*
 4 *human subject or involves an exception from informed*
 5 *consent for emergency research, a sponsor of an inves-*
 6 *tigation of such a test seeking an investigational use*
 7 *exemption shall submit to the Secretary an investiga-*
 8 *tional use application with respect to the in vitro*
 9 *clinical test in accordance with paragraphs (3) and*
 10 *(4).*

11 “(2) *NON-SIGNIFICANT RISK STUDIES.*—*In the*
 12 *case of an in vitro clinical test, the investigational*
 13 *use of which is not described in paragraph (1)—*

14 “(A) *the sponsor of such investigation*
 15 *shall—*

16 “(i) *ensure such investigation is con-*
 17 *ducted in compliance with an investiga-*
 18 *tional plan approved by an institutional re-*
 19 *view committee and the labeling of the in*
 20 *vitro clinical test involved clearly and con-*
 21 *spicuously states, ‘For investigational use*
 22 *only’, as specified in paragraph (4)(A)(ii);*

23 “(ii) *ensure each investigator obtains*
 24 *informed consent as required under part 50,*
 25 *54, and 56 of title 21, Code of Federal Reg-*

1 ulations (or any successor regulations), sub-
2 ject to the exceptions set forth in paragraph
3 (6)(C);

4 “(iii) establish and maintain records
5 with respect to all requirements in this sub-
6 paragraph;

7 “(iv) maintain records and make re-
8 ports as required by the Secretary pursuant
9 to regulations issued under subsection (b);
10 and

11 “(v) ensure that investigators monitor
12 investigations, maintain records and make
13 reports as required by the Secretary pursu-
14 ant to regulations issued under subsection
15 (b); and

16 “(B) the sponsor may rely on any exception
17 or exemption described in paragraph (4) or as
18 established by the Secretary in regulations issued
19 under subsection (b).

20 “(3) APPLICATION.—An investigational use ap-
21 plication shall be submitted in such time and manner
22 and contain such information as the Secretary may
23 require in regulation, and shall include an investiga-
24 tional plan for proposed clinical testing and assur-

1 *ances that the sponsor submitting the application*
 2 *will—*

3 *“(A) establish and maintain records rel-*
 4 *evant to the investigation of such in vitro clin-*
 5 *ical test; and*

6 *“(B) submit to the Secretary annual reports*
 7 *of data obtained as a result of the investigational*
 8 *use of the in vitro clinical test during the period*
 9 *covered by the exemption that the Secretary rea-*
 10 *sonably determines will enable the Secretary—*

11 *“(i) to ensure compliance with the con-*
 12 *ditions for the exemption specified in para-*
 13 *graph (4);*

14 *“(ii) to review the progress of the in-*
 15 *vestigation involved; and*

16 *“(iii) to evaluate the ability to meet*
 17 *the applicable standard.*

18 *“(4) CONDITIONS FOR EXEMPTION.—*

19 *“(A) IN GENERAL.—An application for an*
 20 *investigational use exemption with respect to a*
 21 *significant risk study shall be granted if each of*
 22 *the following conditions is met:*

23 *“(i) The risks to the subjects of the in*
 24 *vitro clinical test are outweighed by the an-*
 25 *ticipated benefits of the test to the subjects*

1 *and the importance of the knowledge to be*
 2 *gained, and adequate assurance of informed*
 3 *consent is provided in accordance with*
 4 *paragraphs (6)(B) and (6)(C).*

5 “(ii) *The proposed labeling for the in*
 6 *vitro clinical test involved clearly and con-*
 7 *spicuously states ‘For investigational use*
 8 *only’.*

9 “(iii) *Such other requirements the Sec-*
 10 *retary determines—*

11 *“(I) are necessary for the protec-*
 12 *tion of the public health and safety;*
 13 *and*

14 *“(II) do not unduly delay inves-*
 15 *tigation.*

16 “(B) *CERTAIN SIGNIFICANT RISK STUDIES*
 17 *OF IN VITRO CLINICAL TESTS FOR AN UNMET*
 18 *NEED.—The Secretary shall not impose a limit*
 19 *on the sample size for a significant risk study of*
 20 *an in vitro clinical test that has received break-*
 21 *through designation under section 587I.*

22 “(5) *COORDINATION WITH INVESTIGATIONAL NEW*
 23 *DRUG APPLICATIONS.—Any requirement for the sub-*
 24 *mission of a report to the Secretary pursuant to an*
 25 *application for an investigational new drug exemp-*

1 *tion involving an in vitro clinical test shall supersede*
2 *the reporting requirement under paragraph (3)(B),*
3 *but only to the extent the requirement with respect to*
4 *the application for exemption with respect to the drug*
5 *is duplicative of the reporting requirement under such*
6 *paragraph.*

7 “(6) *INVESTIGATIONAL PLAN, PROCEDURES, AND*
8 *CONDITIONS.—With respect to an investigational plan*
9 *submitted under paragraph (3), the sponsor submit-*
10 *ting such plan shall—*

11 “(A) *promptly notify the Secretary of the*
12 *approval or the suspension or termination of the*
13 *approval of such plan by an institutional review*
14 *committee;*

15 “(B) *in the case of an in vitro clinical test*
16 *made available to investigators for clinical test-*
17 *ing, obtain agreements from each investigator*
18 *that any testing of the in vitro clinical test in-*
19 *volving human subjects will be under such inves-*
20 *tigator’s supervision and in accordance with*
21 *paragraph (C) and submit such agreements to*
22 *the Secretary that ensure—*

23 “(i) *all investigators will comply with*
24 *this section, regulations promulgated or re-*

1 *vised under this section, and applicable*
2 *human subjects regulations; and*

3 *“(ii) the investigator will ensure*
4 *that—*

5 *“(I) informed consent is obtained*
6 *as required under part 50 of title 21,*
7 *Code of Federal Regulations (or any*
8 *successor regulations), amended to*
9 *apply to in vitro clinical tests; and*

10 *“(II) the requirements for institu-*
11 *tional review board under part 56 of*
12 *title 21 of the Code of Federal Regula-*
13 *tions (or successor regulations), amend-*
14 *ed to apply to in vitro clinical tests,*
15 *are met; and*

16 *“(C) ensure that informed consent will be*
17 *obtained from each human subject (or the rep-*
18 *resentative of such subject) of proposed clinical*
19 *testing involving such in vitro clinical test, ex-*
20 *cept where, subject to such other conditions as the*
21 *Secretary may prescribe—*

22 *“(i) the proposed clinical testing poses*
23 *no more than minimal risk to the human*
24 *subject and includes appropriate safeguards*

1 to protect the rights, safety, and welfare of
2 the human subject; or

3 “(ii) the investigator conducting or su-
4 pervising the clinical testing determines in
5 writing that there exists a life-threatening
6 situation involving the human subject of
7 such testing which necessitates the use of
8 such *in vitro* clinical test and it is not fea-
9 sible to obtain informed consent from the
10 subject and there is not sufficient time to
11 obtain such consent from a representative of
12 such subject.

13 “(7) *CONCURRED BY LICENSED PHYSICIAN.*—The
14 determination required by paragraph (6)(C)(ii) shall
15 be concurred in writing by a licensed physician who
16 is not involved in the testing of the human subject
17 with respect to which such determination is made un-
18 less immediate use of the *in vitro* clinical test is re-
19 quired to save the life of the human subject of such
20 testing and there is not sufficient time to obtain such
21 concurrence.

22 “(8) *SIGNIFICANT RISK.*—For purposes of this
23 subsection, the term ‘significant risk’ means, with re-
24 spect to an *in vitro* clinical test, that the use of such
25 *in vitro* clinical test—

1 “(A) is of substantial importance in per-
 2 forming an activity or activities described in sec-
 3 tion 201(ss)(1) for, a serious or life-threatening
 4 disease or condition without confirmation of the
 5 diagnosis by a medically established diagnostic
 6 product or procedure;

7 “(B) requires an invasive sampling proce-
 8 dure that presents a significant risk to the
 9 human subject, provided that routine
 10 venipuncture shall not be considered an invasive
 11 sampling procedure; or

12 “(C) otherwise presents a potential for seri-
 13 ous risk to the health of a human subject.

14 “(d) REVIEW OF APPLICATIONS.—

15 “(1) IN GENERAL.—The Secretary may issue an
 16 order approving an investigation as proposed, ap-
 17 proving it with conditions or modifications, or dis-
 18 approving it.

19 “(2) FAILURE TO ACT.—Unless the Secretary,
 20 not later than 30 calendar days after the date of the
 21 submission of an application for an investigational
 22 use exemption that meets the requirements of sub-
 23 section (c), issues an order under paragraph (1) and
 24 notifies the sponsor submitting the application, the

1 *application shall be treated as approved as of such*
2 *date without further action by the Secretary.*

3 “(3) *DENIAL.*—*The Secretary may deny an in-*
4 *vestigational use application submitted under this*
5 *subsection if the Secretary determines that the inves-*
6 *tigation with respect to which the application is sub-*
7 *mitted does not conform to the requirements of sub-*
8 *section (c). A notification of such denial submitted to*
9 *the sponsor with respect to such a request shall con-*
10 *tain the order of disapproval and a complete state-*
11 *ment of the reasons for the Secretary’s denial of the*
12 *application.*

13 “(e) *WITHDRAWAL OF EXEMPTION.*—

14 “(1) *IN GENERAL.*—*The Secretary may, by ad-*
15 *ministrative order, withdraw an exemption approved*
16 *under this section with respect to an in vitro clinical*
17 *test, including an exemption treated as approved*
18 *based on the Secretary’s failure to act pursuant to*
19 *subsection (d)(2), if the Secretary determines that an*
20 *investigation conducted under such an exemption does*
21 *not meet the applicable conditions under subsection*
22 *(c)(3) for such exemption.*

23 “(2) *OPPORTUNITY TO BE HEARD.*—

24 “(A) *IN GENERAL.*—*Subject to subpara-*
25 *graph (B), an order withdrawing an investiga-*

1 *tional use exemption granted under this section*
2 *may be issued only after the Secretary provides*
3 *the sponsor of the in vitro clinical test with an*
4 *opportunity for an informal hearing.*

5 *“(B) EXCEPTION.—An order referred to in*
6 *subparagraph (A) with respect to an investiga-*
7 *tional use exemption granted under this section*
8 *may be issued on a preliminary basis before the*
9 *provision of an opportunity for an informal*
10 *hearing if the Secretary determines that the con-*
11 *tinuation of testing under the exemption will re-*
12 *sult in an unreasonable risk to the public health.*
13 *The Secretary will provide an opportunity for*
14 *an informal hearing promptly following any*
15 *preliminary action under this subparagraph.*

16 *“(f) CHANGES.—*

17 *“(1) IN GENERAL.—The regulations promulgated*
18 *under subsection (b) shall provide, with respect to an*
19 *in vitro clinical test for which an exemption under*
20 *this subsection is in effect, procedures and conditions*
21 *under which changes are allowed without the addi-*
22 *tional approval of an application for an exemption or*
23 *submission of a supplement to such an application.*
24 *Such regulations shall provide that such a change*
25 *may be made if—*

1 “(A) the sponsor determines, on the basis of
2 credible information (as defined in regulations)
3 that the change meets the conditions specified in
4 paragraph (2); and

5 “(B) the sponsor submits to the Secretary,
6 not later than 5 calendar days after making the
7 change, a notice of the change.

8 “(2) CONDITIONS.—The conditions specified in
9 this paragraph are that—

10 “(A) in the case of developmental changes to
11 an in vitro clinical test, including manufac-
12 turing changes, the changes—

13 “(i) do not constitute a significant
14 change in design or in basic principles of
15 operation;

16 “(ii) do not affect the rights, safety, or
17 welfare of the human subjects involved in
18 the investigation; and

19 “(iii) are made in response to informa-
20 tion gathered during the course of an inves-
21 tigation; and

22 “(B) in the case of changes to clinical proto-
23 cols applicable to the test, the changes do not af-
24 fect—

1 “(i) the validity of data or information
 2 resulting from the completion of an ap-
 3 proved clinical protocol, or the relationship
 4 of likely patient risk to benefit relied upon
 5 to approve a product;

6 “(ii) the scientific soundness of a plan
 7 submitted under subsection (c)(3); or

8 “(iii) the rights, safety, or welfare of
 9 the human subjects involved in the inves-
 10 tigation.

11 “(g) *CLINICAL HOLD*.—

12 “(1) *IN GENERAL*.—At any time, the Secretary
 13 may impose a clinical hold with respect to an inves-
 14 tigation of an *in vitro* clinical test if the Secretary
 15 makes a written determination described in para-
 16 graph (2). The Secretary shall, in imposing such clin-
 17 ical hold, specify the basis for the clinical hold, in-
 18 cluding the specific information available to the Sec-
 19 retary which served as the basis for such clinical hold,
 20 and confirm such determination in writing. The ap-
 21 plicant may immediately appeal any such determina-
 22 tion pursuant to section 587P.

23 “(2) *DETERMINATION*.—

24 “(A) *IN GENERAL*.—For purposes of para-
 25 graph (1), a determination described in this sub-

1 paragraph with respect to a clinical hold is a de-
 2 termination that, based on credible evidence, the
 3 in vitro clinical test involved represents an un-
 4 reasonable risk to the safety of the persons who
 5 are the subjects of the clinical investigation, tak-
 6 ing into account the qualifications of the clinical
 7 investigators, information about the in vitro
 8 clinical test, the design of the clinical investiga-
 9 tion, the condition for which the in vitro clinical
 10 test is to be investigated, and the health status
 11 of the subjects involved.

12 “(B) REMOVAL OF CLINICAL HOLD.—Any
 13 written request to the Secretary from the sponsor
 14 of an investigation that a clinical hold be re-
 15 moved shall receive a decision, in writing and
 16 specifying the reasons therefor, within 30 days
 17 after receipt of such request. Any such request
 18 shall include sufficient information to support
 19 the removal of such clinical hold.

20 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

21 “(a) ESTABLISHMENT.—Not later than 2 years after
 22 the date of enactment of the VALID Act of 2022, the Sec-
 23 retary shall make available a comprehensive test informa-
 24 tion system for in vitro clinical tests that is designed to—

1 “(1) provide a transparent interface on the
2 website of the Food and Drug Administration for
3 stakeholders, to the extent permitted by applicable
4 law, which may include access to the—

5 “(A) regulatory pathway designation infor-
6 mation for each in vitro clinical test or tests
7 with the same indications for use;

8 “(B) registration and listing information
9 provided by developers under section 587J, in-
10 cluding the use of a link for labels;

11 “(C) adverse event reports submitted under
12 section 587M, as appropriate;

13 “(D) reports of corrections and removals
14 submitted under section 587N; and

15 “(E) other information pertaining to an in
16 vitro clinical test or tests with the same indica-
17 tions for use, as the Secretary determines appro-
18 priate; and

19 “(2) provide a secure portal for electronic sub-
20 mission, including applications and other in vitro
21 clinical test submissions, registration and listing in-
22 formation, and adverse event reports, which provides
23 protections from unauthorized disclosure of informa-
24 tion, including of—

1 “(A) *trade secret or confidential commercial*
2 *or financial information; and*

3 “(B) *information that could compromise*
4 *national security.*

5 “(b) *SUBMISSION FUNCTION.—The comprehensive test*
6 *information system shall serve as the electronic submission*
7 *service for test developers submitting information for appli-*
8 *cations under sections 587B and 587D.*

9 **“SEC. 587U. PREEMPTION.**

10 “(a) *IN GENERAL.—Except as provided in subsection*
11 *(b), no State, Tribal, or local government (or political sub-*
12 *division thereof) may establish or continue in effect any re-*
13 *quirement—*

14 “(1) *that is different from, or in addition to, any*
15 *requirement applicable to an in vitro clinical test*
16 *under this Act; or*

17 “(2) *with respect to the analytical validity, clin-*
18 *ical validity, or safety for individuals who come into*
19 *contact with such an in vitro clinical test.*

20 “(b) *EXCEPTIONS.—Subsection (a) shall not be con-*
21 *strued to affect the authority of a State, Tribal, or local*
22 *government to do any of the following:*

23 “(1) *To license laboratory personnel, health care*
24 *practitioners, or health care facilities or to regulate*

1 *any aspect of a health care practitioner-patient rela-*
 2 *tionship.*

3 *“(2) To enforce laws of general applicability,*
 4 *such as zoning laws, environmental laws, labor laws,*
 5 *and general business laws.*

6 *“(3) To authorize laboratories to develop and*
 7 *perform an in vitro clinical test, pursuant to a law*
 8 *enacted by a State prior to January 1, 2022, as long*
 9 *as such law does not impose requirements that are*
 10 *different from any requirement applicable to an in*
 11 *vitro clinical test under this Act. If a State has en-*
 12 *acted such a law, the Secretary shall exempt such test*
 13 *for laboratories in that State from compliance with*
 14 *this subchapter.*

15 *“(c) CLARIFICATION.—Nothing in this section shall be*
 16 *construed to—*

17 *“(1) modify any action for damages or the li-*
 18 *ability of any person under the law of any State; or*

19 *“(2) shift liability to health care practitioners or*
 20 *other users.*

21 **“SEC. 587V. ADULTERATION.**

22 *“An in vitro clinical test shall be deemed to be adulter-*
 23 *ated:*

24 *“(1) If it consists in whole or in part of any*
 25 *filthy, putrid, or decomposed substance.*

1 “(2) *If it has been developed, prepared, packed,*
2 *or held under insanitary conditions whereby it may*
3 *have been contaminated with filth, or whereby it may*
4 *have been rendered injurious to health.*

5 “(3) *If its container or package is composed, in*
6 *whole or in part, of any poisonous or deleterious sub-*
7 *stance which may render the contents injurious to*
8 *health.*

9 “(4) *If it bears or contains, for purposes of color-*
10 *ing only, a color additive which is unsafe within the*
11 *meaning of section 721(a).*

12 “(5) *If its analytical or clinical validity, as ap-*
13 *plicable, or with respect to a specimen receptacle, its*
14 *safety, falls below that which it purports or is rep-*
15 *resented to possess.*

16 “(6) *If it is required to be, declared to be, pur-*
17 *ports to be, or is represented as being, in conformity*
18 *with any performance standard established or recog-*
19 *nized under section 587R and is not in conformity*
20 *with such standard.*

21 “(7) *If it is required to be in compliance with*
22 *mitigating measures established under section 587E*
23 *and is not in conformity with such mitigating meas-*
24 *ures.*

1 “(8) *If it fails to have in effect an approved pre-*
2 *market application under section 587B, unless such*
3 *in vitro clinical test is in compliance with the re-*
4 *quirements for—*

5 “(A) *offering without an approved pre-*
6 *market application under section 587D(b)(1);*

7 “(B) *an exemption from premarket ap-*
8 *proval under section 587C or 587G; or*

9 “(C) *investigational use pursuant to section*
10 *587S.*

11 “(9) *If it is not in conformity with any condi-*
12 *tion established under section 587B or 587D.*

13 “(10) *If it purports to be an in vitro clinical test*
14 *subject to an exemption under section 587C and it*
15 *fails to meet or maintain any criteria, condition, or*
16 *requirement of such exemption.*

17 “(11) *If it has been granted an exemption under*
18 *section 587S for investigational use, and the person*
19 *granted such exemption or any investigator who uses*
20 *such in vitro clinical test under such exemption fails*
21 *to comply with a requirement prescribed by or under*
22 *such section.*

23 “(12) *If it fails to meet the quality requirements*
24 *prescribed in or established under section 587K (as*
25 *applicable), or the methods used in, or facilities or*

1 *controls used for, its development, packaging, storage,*
 2 *or installation are not in conformity with applicable*
 3 *requirements established under such section.*

4 “(13) *If it has been developed, processed, pack-*
 5 *aged, or held in any establishment, factory, or ware-*
 6 *house and the owner, operator or agent of such estab-*
 7 *lishment, factory, or warehouse delays, denies, or lim-*
 8 *its an inspection, or refuses to permit entry or inspec-*
 9 *tion.*

10 “(14) *If it is not in compliance with any restric-*
 11 *tion required under section 587O.*

12 **“SEC. 587W. MISBRANDING.**

13 *“An in vitro clinical test shall be deemed to be mis-*
 14 *branded:*

15 “(1) *If its labeling is false or misleading in any*
 16 *particular.*

17 “(2) *If in a package form unless it bears a label*
 18 *containing—*

19 “(A) *the name and place of business of the*
 20 *test developer, packager, or distributor; and*

21 “(B) *an accurate statement of the quantity*
 22 *of contents in terms of weight, measure, or nu-*
 23 *merical count with respect to small packages,*
 24 *unless an exemption is granted by the Secretary*
 25 *by the issuance of guidance.*

1 “(3) If any word, statement, or other informa-
2 tion required by or under authority of this Act to ap-
3 pear on the label or labeling, including a test report,
4 is not prominently placed thereon with such conspicu-
5 ousness (as compared with other words, statements,
6 designs, or devices, in the labeling) and in such terms
7 as to render it likely to be read and understood by
8 the ordinary individual under customary conditions
9 of purchase and use.

10 “(4) Unless its labeling bears adequate directions
11 for use and such adequate warnings as are necessary
12 for the protection of users of the in vitro clinical test
13 and recipients of the results of such in vitro clinical
14 test, including patients, consumers, donors, and re-
15 lated health care professionals. Required labeling for
16 in vitro clinical tests intended for use in health care
17 facilities, blood establishments, or by a health care
18 professional may be made available solely by elec-
19 tronic means, provided that the labeling complies
20 with all applicable requirements of law, and that the
21 test developer, or distributor affords such users the op-
22 portunity to request the labeling in paper form, and
23 after such request, promptly provides the requested in-
24 formation without additional cost.

1 “(5) *If there is a reasonable probability that it*
2 *could cause serious or adverse health consequences or*
3 *death, including through absence, delay, or dis-*
4 *continuation in diagnosis or treatment, when used in*
5 *the manner prescribed, recommended, or suggested in*
6 *the labeling thereof.*

7 “(6) *If it was developed, sterilized, packaged, re-*
8 *packaged, relabeled, installed, or imported in an es-*
9 *tablishment not duly registered under section 587J or*
10 *it was not included in a listing under section 587J,*
11 *in accordance with timely reporting requirements*
12 *under this subchapter.*

13 “(7) *In the case of any in vitro clinical test sub-*
14 *ject to restrictions under section 587O, (1) if its ad-*
15 *vertising is false or misleading in any particular, (2)*
16 *if it is offered for clinical use, sold, distributed, or*
17 *used in violation of such restrictions, or (3) unless the*
18 *test developer or distributor includes in all advertise-*
19 *ments and other descriptive printed matter that such*
20 *person issues or causes to be issued, a brief statement*
21 *of the indications for use of the in vitro clinical test*
22 *and relevant warnings, precautions, side effects, and*
23 *contraindications. This paragraph shall not be appli-*
24 *cable to any printed matter that the Secretary deter-*
25 *mines to be labeling as defined in section 201(m).*

1 “(8) *If it is subject to a mitigating measure es-*
 2 *tablished under section 587E and does not bear such*
 3 *labeling as may be prescribed in such mitigating*
 4 *measure.*

5 “(9) *If it is subject to a standard established*
 6 *under section 587R and it does not bear such labeling*
 7 *as may be prescribed in such standard.*

8 “(10) *Unless it bears such labeling as may be re-*
 9 *quired by or established under an applicable labeling*
 10 *requirement under this Act.*

11 “(11) *If there was a failure to comply with any*
 12 *requirement prescribed in or under section 587D,*
 13 *587J, 587K, 587L, 587M, 587N, 587X, 587Y, 587Z,*
 14 *or to provide any report, material, or other informa-*
 15 *tion required with respect to in vitro clinical tests*
 16 *under this subchapter.*

17 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

18 “(a) *IN GENERAL.—*

19 “(1) *IN GENERAL.—In addition to other applica-*
 20 *ble requirements under this Act, the Secretary may*
 21 *issue an order requiring a developer of a high-risk or*
 22 *moderate-risk in vitro clinical test to conduct*
 23 *postmarket surveillance of such in vitro clinical test,*
 24 *if the failure of the in vitro clinical test is reasonably*

1 *likely to result in serious adverse health consequences*
2 *or death from use of such in vitro clinical test.*

3 “(2) *CONSIDERATION.*—*In determining whether*
4 *to require a developer to conduct postmarket surveil-*
5 *lance of an in vitro clinical test, the Secretary shall*
6 *take into consideration the benefits and risks for the*
7 *patient and the least burdensome requirements under*
8 *section 587AA(c).*

9 “(b) *SURVEILLANCE APPROVAL.*—

10 “(1) *IN GENERAL.*—*Each developer required to*
11 *conduct surveillance of an in vitro clinical test shall*
12 *submit, within 30 days of receiving an order from the*
13 *Secretary, a plan for the required surveillance. The*
14 *Secretary, within 60 days of the receipt of such plan,*
15 *shall determine if the person designated to conduct the*
16 *surveillance has the appropriate qualifications and*
17 *experience to undertake such surveillance and if the*
18 *plan will result in useful data that can reveal unfore-*
19 *seen adverse events or other information necessary to*
20 *protect the health of patients or the public.*

21 “(2) *TIMELINE.*—*The developer shall commence*
22 *surveillance under this section not later than 15*
23 *months after the day on which the Secretary orders*
24 *such postmarket surveillance, unless the Secretary de-*

1 *termines more time is needed to commence surveil-*
 2 *lance.*

3 “(3) *PROSPECTIVE SURVEILLANCE.*—*The Sec-*
 4 *retary may order a prospective surveillance period of*
 5 *up to 3 years. Any determination by the Secretary*
 6 *that a longer period is necessary shall be made by*
 7 *mutual agreement between the Secretary and the de-*
 8 *veloper or, if no agreement can be reached, upon the*
 9 *completion of a dispute resolution process pursuant to*
 10 *section 562.*

11 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

12 “(a) *IN GENERAL.*—*All submissions to the Food and*
 13 *Drug Administration with respect to an in vitro clinical*
 14 *test, unless otherwise agreed to by the Secretary, shall—*

15 “(1) *be made electronically; and*

16 “(2) *with respect to the information required*
 17 *under sections 587B and 587D, utilize the system de-*
 18 *scribed in section 587T.*

19 “(b) *ELECTRONIC FORMAT.*—*Beginning on such date*
 20 *as the Secretary specifies in final guidance issued under*
 21 *subsection (c), submissions for in vitro clinical tests, includ-*
 22 *ing recommendations submitted by accredited and recog-*
 23 *nized persons under section 587Q, and any appeals of ac-*
 24 *tion taken by the Secretary with respect to such submis-*

1 sions, shall be submitted in such electronic format as speci-
 2 fied by the Secretary in such guidance.

3 “(c) *GUIDANCE.*—The Secretary shall issue guidance
 4 implementing this section. Such guidance may—

5 “(1) provide standards for the electronic submis-
 6 sion required under subsection (a) or the submission
 7 in electronic format required under subsection (b);

8 “(2) set forth criteria for waivers of, or exemp-
 9 tions from, the requirements of subsection (a) or (b);
 10 and

11 “(3) provide any other information for the effi-
 12 cient implementation and enforcement of this section.

13 **“SEC. 587Z. POSTMARKET REMEDIES.**

14 “(a) *SAFETY NOTICE.*—

15 “(1) *IN GENERAL.*—If the Secretary determines
 16 that an *in vitro* clinical test presents an unreasonable
 17 risk of substantial harm to the public health, and no-
 18 tification under this subsection is necessary to elimi-
 19 nate the unreasonable risk of such harm and no more
 20 practicable means is available under the provisions of
 21 this Act (other than this section) to eliminate the risk,
 22 the Secretary may issue such order as may be nec-
 23 essary to ensure that adequate safety notice is pro-
 24 vided in an appropriate form, by the persons and
 25 means best suited under the circumstances, to all

1 *health care professionals who prescribe, order, or use*
2 *the in vitro clinical test and to any other person (in-*
3 *cluding developers, importers, distributors, retailers,*
4 *and users) who should properly receive such notice.*

5 “(2) NOTICE TO INDIVIDUALS.—An order under
6 *this subsection shall require that the individuals sub-*
7 *ject to the risk with respect to which the order is to*
8 *be issued be included in the persons to be notified of*
9 *the risk unless the Secretary determines that notice to*
10 *such individuals would present a greater danger to*
11 *the health of such individuals than no such notice. If*
12 *the Secretary makes such a determination with re-*
13 *spect to such individuals, the order shall require the*
14 *health care professionals who prescribed, ordered, or*
15 *used the in vitro clinical test provide notification to*
16 *the individuals for whom the health professionals pre-*
17 *scribed, ordered, or used such test, of the risk pre-*
18 *sented by such in vitro clinical test and of any action*
19 *which may be taken by or on behalf of such individ-*
20 *uals to eliminate or reduce such risk. Before issuing*
21 *an order under this subsection, the Secretary shall*
22 *consult with the persons required to give notice under*
23 *the order.*

24 “(b) REPAIR, REPLACEMENT, OR REFUND.—

1 “(1) *DETERMINATION AFTER AN INFORMAL*
2 *HEARING.*—

3 “(A) *IN GENERAL.*—*If, after affording op-*
4 *portunity for an informal hearing, the Secretary*
5 *determines that—*

6 “(i) *an in vitro clinical test presents*
7 *an unreasonable risk of substantial harm to*
8 *the public health;*

9 “(ii) *there are reasonable grounds to*
10 *believe that the in vitro clinical test was not*
11 *properly developed or manufactured consid-*
12 *ering the state of the art as it existed at the*
13 *time of its development;*

14 “(iii) *there are reasonable grounds to*
15 *believe that the unreasonable risk was not*
16 *caused by failure of a person other than a*
17 *developer, importer, distributor, or retailer*
18 *of the in vitro clinical test to exercise due*
19 *care in the installation, maintenance, re-*
20 *pair, or use of the in vitro clinical test; and*

21 “(iv) *the notice authorized by sub-*
22 *section (a) would not by itself be sufficient*
23 *to eliminate the unreasonable risk and ac-*
24 *tion described in paragraph (2) of this sub-*
25 *section is necessary to eliminate such risk,*

1 the Secretary may order the developer, importer,
2 or any distributor of such in vitro clinical test,
3 or any combination of such persons, to submit to
4 him within a reasonable time a plan for taking
5 one or more of the actions described in para-
6 graph (2). An order issued under the preceding
7 sentence which is directed to more than one per-
8 son shall specify which person may decide which
9 action shall be taken under such plan and the
10 person specified shall be the person who the Sec-
11 retary determines bears the principal, ultimate
12 financial responsibility for action taken under
13 the plan unless the Secretary cannot determine
14 who bears such responsibility or the Secretary
15 determines that the protection of the public
16 health requires that such decision be made by a
17 person (including a health professional or user of
18 the in vitro clinical test) other than the person
19 the Secretary determines bears such responsi-
20 bility.

21 “(B) SECRETARY APPROVAL OF PLAN.—The
22 Secretary shall approve a plan submitted pursu-
23 ant to an order issued under subparagraph (A)
24 unless the Secretary determines (after affording
25 opportunity for an informal hearing) that the

1 *action or actions to be taken under the plan or*
2 *the manner in which such action or actions are*
3 *to be taken under the plan will not assure that*
4 *the unreasonable risk with respect to which such*
5 *order was issued will be eliminated. If the Sec-*
6 *retary disapproves a plan, the Secretary shall*
7 *order a revised plan to be submitted within a*
8 *reasonable time. If the Secretary determines*
9 *(after affording opportunity for an informal*
10 *hearing) that the revised plan is unsatisfactory*
11 *or if no revised plan or no initial plan has been*
12 *submitted to the Secretary within the prescribed*
13 *time, the Secretary shall—*

14 *“(i) prescribe a plan to be carried out*
15 *by the person or persons to whom the order*
16 *issued under subparagraph (A) was di-*
17 *rected; or*

18 *“(ii) after affording an opportunity for*
19 *an informal hearing, by order prescribe a*
20 *plan to be carried out by a person who is*
21 *a developer, importer, distributor, or re-*
22 *tailer of the in vitro clinical test with re-*
23 *spect to which the order was issued but to*
24 *whom the order under subparagraph (A)*
25 *was not directed.*

1 “(2) *ACTIONS ON A PLAN.*—*The actions that may*
2 *be taken under a plan submitted under an order*
3 *issued under paragraph (1)(A) are as follows:*

4 “(A) *To repair the in vitro clinical test so*
5 *that it does not present the unreasonable risk of*
6 *substantial harm with respect to which the order*
7 *under paragraph (1)(A) was issued.*

8 “(B) *To replace the in vitro clinical test*
9 *with a like or equivalent test which is in con-*
10 *formity with all applicable requirements of this*
11 *Act.*

12 “(C) *To refund the purchase price of the in*
13 *vitro clinical test (less a reasonable allowance for*
14 *use if such in vitro clinical test has been in the*
15 *possession of the user for one year or more at the*
16 *time of notice ordered under subsection (a), or at*
17 *the time the user receives actual notice of the un-*
18 *reasonable risk with respect to which the order*
19 *was issued under paragraph (1)(A), whichever*
20 *occurs first).*

21 “(3) *NO CHARGE.*—*No charge shall be made to*
22 *any person (other than a developer, importer, dis-*
23 *tributor, or retailer) for using a remedy described in*
24 *paragraph (2) and provided under an order issued*
25 *under paragraph (1), and the person subject to the*

1 order shall reimburse each person (other than a devel-
 2 oper, manufacturer, importer, distributor, or retailer)
 3 who is entitled to such a remedy for any reasonable
 4 and foreseeable expenses actually incurred by such
 5 person in using such remedy.

6 “(c) *REIMBURSEMENT.*—An order issued under sub-
 7 section (b)(1)(A) with respect to an *in vitro* clinical test
 8 may require any person who is a developer, importer, dis-
 9 tributor, or retailer of the *in vitro* clinical test to reimburse
 10 any other person who is a developer, importer, distributor,
 11 or retailer of such *in vitro* clinical test for such other per-
 12 son’s expenses actually incurred in connection with car-
 13 rying out the order if the Secretary determines such reim-
 14 bursement is required for the protection of the public health.
 15 Any such requirement shall not affect any rights or obliga-
 16 tions under any contract to which the person receiving re-
 17 imbursement or the person making such reimbursement is
 18 a party.

19 “(d) *RECALL AUTHORITY.*—

20 “(1) *IN GENERAL.*—If the Secretary finds that
 21 there is a reasonable probability that an *in vitro* clin-
 22 ical test approved under section 587B or offered
 23 under a technology certification order under section
 24 587D would cause serious, adverse health consequences
 25 or death, including by the absence, significant delay,

1 or discontinuation of appropriate medical treatment,
 2 the Secretary shall issue an order requiring the ap-
 3 propriate person (including the developers, importers,
 4 distributors, or retailers of the *in vitro* clinical test)—

5 “(A) to immediately cease distribution of
 6 such *in vitro* clinical test; and

7 “(B) to immediately notify health profes-
 8 sionals and applicable *in vitro* clinical test user
 9 facilities of the order and to instruct such profes-
 10 sionals and facilities to cease use of such *in vitro*
 11 clinical test.

12 “(2) *INFORMAL HEARING.*—The order issued
 13 under paragraph (1)(A), shall provide the person sub-
 14 ject to the order with an opportunity for an informal
 15 hearing, to be held not later than 10 calendar days
 16 after the date of the issuance of the order, on the ac-
 17 tions required by the order and on whether the order
 18 should be amended to require a recall of such *in vitro*
 19 clinical test. If, after providing an opportunity for
 20 such a hearing, the Secretary determines that inad-
 21 equate grounds exist to support the actions required
 22 by the order, the Secretary shall vacate the order.

23 “(3) *AMENDED ORDER.*—

24 “(A) *IN GENERAL.*—If, after providing an
 25 opportunity for an informal hearing under

1 paragraph (2), the Secretary determines that the
2 order should be amended to include a recall of
3 the *in vitro* clinical test with respect to which the
4 order was issued, the Secretary shall, except as
5 provided in subparagraph (B), amend the order
6 to require a recall. The Secretary shall specify a
7 timetable in which the recall will occur and shall
8 require periodic reports describing the progress of
9 the recall.

10 “(B) *REQUIREMENTS.*—An amended order
11 under subparagraph (A)—

12 “(i) shall not include recall of the *in*
13 *vitro* clinical test from individuals;

14 “(ii) shall not include recall of an *in*
15 *vitro* clinical test from test user facilities if
16 the Secretary determines that the risk of re-
17 calling such *in vitro* clinical test from the
18 facilities presents a greater health risk than
19 the health risk of not recalling the *in vitro*
20 clinical test from use; and

21 “(iii) shall provide for notice to indi-
22 viduals subject to the risks associated with
23 the use of such *in vitro* clinical test. In pro-
24 viding the notice required by this clause, the
25 Secretary may use the assistance of health

1 professionals who prescribed, ordered, or
 2 used such an *in vitro* clinical test for indi-
 3 viduals.

4 “(4) *CLARIFICATION.*—The remedy provided by
 5 this subsection shall be in addition to remedies pro-
 6 vided by subsections (a), (b), and (c).

7 **“SEC. 587AA. APPLICABILITY.**

8 “(a) *IN GENERAL.*—An *in vitro* clinical test shall be
 9 subject to the requirements of this subchapter, except as oth-
 10 erwise provided in this subchapter. Laboratory operations
 11 shall not be subject to the requirements of this subchapter.

12 “(b) *INTERSTATE COMMERCE.*—Any *in vitro* clinical
 13 test that is offered, including by making available for clin-
 14 ical use in the United States is deemed to be an act that
 15 constitutes introduction into interstate commerce for pur-
 16 poses of enforcing the requirements of this Act.

17 “(c) *LEAST BURDENSOME REQUIREMENTS.*—

18 “(1) *IN GENERAL.*—In carrying out this sub-
 19 chapter, the Secretary shall consider the least burden-
 20 some means necessary to meet the applicable stand-
 21 ard, and other regulatory requirements, as determined
 22 by the Secretary.

23 “(2) *NECESSARY DEFINED.*—For purposes of
 24 paragraph (1), the term ‘necessary’ means the min-
 25 imum required information that would support a de-

1 *termination by the Secretary that the application*
 2 *meet the applicable standard or regulatory require-*
 3 *ment, as determined by the Secretary.*

4 “(d) *SERVICE OF ORDERS.*—*Orders of the Secretary*
 5 *under this section with respect to applications under sub-*
 6 *section (a) or (b) of section 587B or supplements under sub-*
 7 *section (f) of such section shall be served—*

8 “(1) *in person by any officer or employee of the*
 9 *Department of Health and Human Services des-*
 10 *ignated by the Secretary; or*

11 “(2) *by mailing the order by registered mail or*
 12 *certified mail or electronic equivalent addressed to the*
 13 *applicant at the last known address in the records of*
 14 *the Secretary.*

15 “(e) *LABORATORIES AND BLOOD AND TISSUE ESTAB-*
 16 *LISHMENTS.*—

17 “(1) *RELATION TO LABORATORY CERTIFICATION*
 18 *PURSUANT TO SECTION 353 OF THE PUBLIC HEALTH*
 19 *SERVICE ACT.*—*Nothing in this subchapter shall be*
 20 *construed to modify the authority of the Secretary*
 21 *with respect to laboratories or clinical laboratories*
 22 *under section 353 of the Public Health Service Act.*

23 “(2) *AVOIDING DUPLICATION.*—*In implementing*
 24 *this subchapter, the Secretary shall avoid issuing or*
 25 *enforcing regulations or guidance that are duplicative*

1 *of regulations or guidance under section 353 of the*
2 *Public Health Service Act.*

3 “(3) *BLOOD AND TISSUE.*—*Nothing in this sub-*
4 *chapter shall be construed to modify the authority of*
5 *the Secretary with respect to laboratories, establish-*
6 *ments, or other facilities to the extent they are en-*
7 *gaged in the propagation, manufacture, or prepara-*
8 *tion, including filling, labeling, packaging, and stor-*
9 *age, of blood, blood components, human cells, tissues,*
10 *or tissue products pursuant to any requirements*
11 *under this Act or section 351 or 361 of the Public*
12 *Health Service Act.*

13 “(f) *NOT COMBINATION PRODUCT.*—*A product con-*
14 *stituted of a device and an in vitro clinical test is not a*
15 *combination product and shall be regulated as a device.*

16 “(g) *PRACTICE OF MEDICINE.*—*Nothing in this sub-*
17 *chapter shall be construed to limit or interfere with the au-*
18 *thority of a health care practitioner to prescribe or admin-*
19 *ister any lawfully offered in vitro clinical test for any con-*
20 *dition or disease within a legitimate health care practi-*
21 *tioner-patient relationship pursuant to applicable Federal*
22 *or State law.*

23 “(h) *SALE, DISTRIBUTION, LABELING.*—*Nothing in*
24 *this section shall be construed to limit the authority of the*
25 *Secretary to establish or enforce restrictions on the sale, dis-*

1 *tribution, or labeling of an in vitro clinical test under this*
 2 *Act.*

3 “(i) *PROMOTION OF UNAPPROVED USES.*—*Nothing in*
 4 *this section shall be construed to alter any prohibition on*
 5 *the promotion of unapproved uses of legally marketed in*
 6 *vitro clinical tests.*

7 **“SEC. 587BB. JUDICIAL REVIEW.**

8 “(a) *IN GENERAL.*—*Not later than 30 days after an*
 9 *order issued pursuant to sections 587B or 587D, any person*
 10 *adversely affected by such order may file a petition with*
 11 *the United States Court of Appeals for the District of Co-*
 12 *lumbia or for the circuit wherein such person resides or has*
 13 *a principal place of business for judicial review of such*
 14 *order, in accordance with the procedure set forth in section*
 15 *517(a).*

16 “(b) *APPLICATION OF PROVISIONS.*—*Subsections (a)*
 17 *through (e) of section 517 shall apply with respect to a peti-*
 18 *tion under subsection (a) of this section in the same manner*
 19 *such subsections apply to a petition under section 517. Sub-*
 20 *section (f) of section 517 shall apply to an order issued*
 21 *under section 587B or 587D.”.*

22 **SEC. 824. ENFORCEMENT AND OTHER PROVISIONS.**

23 (a) *PROHIBITED ACTS.*—*Section 301 of the Federal*
 24 *Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended*
 25 *by section 811, is further amended—*

1 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),
 2 (r), and (y), by inserting “in vitro clinical test,” after
 3 “device,” each place it appears;

4 (2) in paragraph (g), by inserting after “mis-
 5 branded”, “, and the development within any Terri-
 6 tory of any in vitro clinical test that is adulterated
 7 or misbranded”;

8 (3) in paragraph (y), by inserting “or 587Q”
 9 after “section 523” each place it appears;

10 (4) in paragraph (ff), by striking “or device”
 11 and inserting “, device, or in vitro clinical test”; and

12 (5) by adding at the end, the following:

13 “(kkk)(1) Forging, counterfeiting, simulating, or false-
 14 ly representing, or without proper authority using any
 15 mark, stamp, tag, label, or other identification upon any
 16 in vitro clinical test or container, packaging, or labeling
 17 thereof so as to render such in vitro clinical test a counter-
 18 feit in vitro clinical test.

19 “(2) Making, selling, disposing of, or keeping in posses-
 20 sion, control, or custody, or concealing any punch, die,
 21 plate, stone, or other thing designed to print, imprint, or
 22 reproduce the trademark, trade name, or other identifying
 23 mark or imprint of another or any likeness of any of the
 24 foregoing upon any in vitro clinical test or container, pack-

1 aging, or labeling thereof so as to render such in vitro clin-
 2 ical test a counterfeit in vitro clinical test.

3 “(3) The doing of any act which causes an in vitro
 4 clinical test to be a counterfeit in vitro clinical test, or the
 5 sale or dispensing, or the holding for sale or dispensing,
 6 of a counterfeit in vitro clinical test.

7 “(III)(1) The introduction or delivery for introduction
 8 into interstate commerce of an in vitro clinical test in viola-
 9 tion of section 587A(a).

10 “(2) The making of a false, fraudulent, or deceptive
 11 statement about an in vitro clinical test that is exempt from
 12 premarket review under section 587C.

13 “(3) The failure to maintain complete and accurate
 14 documentation for an exemption as required under section
 15 587C or the failure to provide labeling required under sec-
 16 tion 587L.

17 “(4) With respect to an in vitro clinical test, the sub-
 18 mission of any report or listing under this Act that is false
 19 or misleading in any material respect.

20 “(5) The failure to comply with a condition of ap-
 21 proval, or restriction required under an approved applica-
 22 tion under section 587B; the failure to perform a risk anal-
 23 ysis required by section 587B; the failure to submit an an-
 24 nual update required under section 587J(c)(2)(B); or the

1 *failure to complete postmarket surveillance as required*
2 *under section 587X.*

3 “(6) *The failure to comply with applicable require-*
4 *ments to submit an application or report under section*
5 *587D(e).*

6 “(7) *The failure to comply with applicable mitigating*
7 *measures established under section 587E or to submit,*
8 *maintain, or make available the documentation required*
9 *under section 587E(b); or the failure to comply with appli-*
10 *cable performance standards established under section*
11 *587R.*

12 “(8) *The failure to register in accordance with section*
13 *587J, the failure to provide information required under sec-*
14 *tion 587J(b), or the failure to maintain or submit informa-*
15 *tion required under section 587J(c).*

16 “(9) *The failure to comply with requirements under*
17 *section 587M or 587N, the failure to comply with a restric-*
18 *tion required under section 587O, or the failure to comply*
19 *with labeling and advertising requirements under section*
20 *587O(b).*

21 “(10) *The failure to comply with the requirements of*
22 *section 587Q.*

23 “(11) *The failure to comply with any requirement of*
24 *section 587S; the failure to furnish any notification, infor-*
25 *mation, material, or report required under section 587S;*

1 *or the failure to comply with an order issued under section*
 2 *587S.*

3 “(12) *The failure to furnish information requested by*
 4 *the Secretary under 587G(d)(2).”.*

5 (b) *PENALTIES.*—*Section 303 of the Federal Food,*
 6 *Drug, and Cosmetic Act (21 U.S.C. 333) is amended—*

7 (1) *in subsection (b)(8), by inserting “or coun-*
 8 *terfeit in vitro clinical test” after “counterfeit drug”;*

9 (2) *in subsection (c)—*

10 (A) *by striking “; or (5)” and inserting “;*
 11 *(5)”;* and

12 (B) *by inserting before the period at the end*
 13 *the following: “; or (6) for having violated sec-*
 14 *tion 301(kkk)(2) if such person acted in good*
 15 *faith and had no reason to believe that use of the*
 16 *punch, die, plate, stone, or other thing involved*
 17 *would result in an in vitro clinical test being a*
 18 *counterfeit in vitro clinical test, or for having*
 19 *violated section 301(kkk)(3) if the person doing*
 20 *the act or causing it to be done acted in good*
 21 *faith and had no reason to believe that the in*
 22 *vitro clinical test was a counterfeit in vitro clin-*
 23 *ical test”;* and

24 (3) *in subsection (f)(1)—*

25 (A) *in subparagraph (A)—*

1 (i) by inserting “or in vitro clinical
2 tests” after “which relates to devices”;

3 (ii) by inserting “or section
4 587Q(a)(1)” after “section 704(g)”; and

5 (iii) by inserting “or in vitro clinical
6 tests, as applicable” before the period at the
7 end of the second sentence; and

8 (B) in subparagraph (B)(i), by striking “or
9 520(f)” and inserting “, 520(f), 587K, or
10 587M,”.

11 (c) *SEIZURE*.—Section 304 of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 334) is amended—

13 (1) in subsection (a)(2)—

14 (A) by striking “, and (E)” and inserting
15 “, (E)”; and

16 (B) by inserting before the period at the end
17 the following: “, and (F) Any in vitro clinical
18 test that is a counterfeit in vitro clinical test,
19 (G) Any container, packaging, or labeling of a
20 counterfeit in vitro clinical test, and (H) Any
21 punch, die, plate, stone, labeling, container, or
22 other thing used or designed for use in making
23 a counterfeit in vitro clinical test”;

24 (2) in subsection (d)(1), by inserting “in vitro
25 clinical test,” after “device,”; and

1 (3) in subsection (g)—

2 (A) in paragraph (1), by inserting “, in
3 *vitro clinical test*,” after “device” each place it
4 appears; and

5 (B) in paragraph (2)—

6 (i) in subparagraph (A), by inserting
7 “, in *vitro clinical test*,” after “device”; and

8 (ii) in subparagraph (B), by inserting
9 “or in *vitro clinical test*” after “device”
10 each place it appears.

11 (d) *DEBARMENT, TEMPORARY DENIAL OF APPROVAL,*
12 *AND SUSPENSION.*—Section 306 of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 335a) is amended by adding
14 at the end the following:

15 “(n) *IN VITRO CLINICAL TESTS; MANDATORY DEBAR-*
16 *MENT REGARDING THIRD-PARTY INSPECTIONS AND RE-*
17 *VIEWS.*—

18 “(1) *IN GENERAL.*—If the Secretary finds that a
19 person has been convicted of a felony for a violation
20 of section 301(gg) or 301(kkk)(1), the Secretary shall
21 debar such person from being accredited under section
22 587Q and from carrying out activities under an
23 agreement described in section 803(b).

1 “(2) *DEBARMENT PERIOD.*—*The Secretary shall*
 2 *debar a person under paragraph (1) for the following*
 3 *periods:*

4 “(A) *The period of debarment of a person*
 5 *(other than an individual) shall not be less than*
 6 *1 year or more than 10 years, but if an act lead-*
 7 *ing to a subsequent debarment under such para-*
 8 *graph occurs within 10 years after such person*
 9 *has been debarred under such paragraph, the pe-*
 10 *riod of debarment shall be permanent.*

11 “(B) *The debarment of an individual shall*
 12 *be permanent.*

13 “(3) *TERMINATION OF DEBARMENT; JUDICIAL*
 14 *REVIEW; OTHER MATTERS.*—*Subsections (c)(3), (d),*
 15 *(e), (i), (j), and (l)(1) apply with respect to a person*
 16 *(other than an individual) or an individual who is*
 17 *debarred under paragraph (1) to the same extent and*
 18 *in the same manner as such subsections apply with*
 19 *respect to a person who is debarred under subsection*
 20 *(a)(1), or an individual who is debarred under sub-*
 21 *section (a)(2), respectively.”.*

22 “(e) *EXPANDED ACCESS TO UNAPPROVED THERAPIES*
 23 *AND DIAGNOSTICS.*—*Section 561 of the Federal Food, Drug,*
 24 *and Cosmetic Act (21 U.S.C. 360bbb) is amended—*

25 *(1) in subsections (a) through (d)—*

1 (A) by striking “or investigational devices”
 2 each place it appears and inserting “, investiga-
 3 tional devices, or investigational in vitro clinical
 4 tests”; and

5 (B) by striking “or investigational device”
 6 each place it appears (other than the second such
 7 place in paragraph (3)(A)) of subsection (c)) and
 8 inserting “, investigational device, or investiga-
 9 tional in vitro clinical test”;

10 (2) in subsection (b)(4) by striking “or 520(g)”
 11 each place it appears and inserting “, 520(g), or
 12 587S”;

13 (3) in subsection (c)—

14 (A) by amending the subsection heading to
 15 read: “TREATMENT INVESTIGATIONAL NEW
 16 DRUG APPLICATIONS, TREATMENT INVESTIGA-
 17 TIONAL DEVICE EXEMPTIONS, AND TREATMENT
 18 INVESTIGATIONAL IN VITRO CLINICAL TEST EX-
 19 EMPTIONS.”;

20 (B) in paragraph (3)(A), by striking “or
 21 investigational device exemption in effect under
 22 section 520(g)” and inserting “, investigational
 23 device exemption in effect under section 520(g),
 24 or investigational in vitro clinical test exemption
 25 under section 587S”;

1 (C) by striking “or treatment investiga-
 2 tional device exemption” each place it appears
 3 and inserting “, treatment investigational device
 4 exemption, or treatment investigational in vitro
 5 clinical test exemption”;

6 (D) in paragraph (5), by striking “or
 7 520(g)” and inserting “, 520(g), or 587S”; and

8 (E) in the matter following paragraph (7)
 9 by striking “or 520(g)” each place it appears
 10 and inserting “, 520(g), or 587S”; and

11 (4) by amending subsection (e) to read as fol-
 12 lows:

13 “(e) *DEFINITIONS.*—In this section, the terms ‘inves-
 14 tigational drug’, ‘investigational device’, ‘investigational in
 15 vitro clinical test’, ‘treatment investigational new drug ap-
 16 plication’, ‘treatment investigational device exemption’,
 17 and ‘treatment investigational in vitro clinical test exemp-
 18 tion’ shall have the meanings given the terms in regulations
 19 prescribed by the Secretary.”.

20 (f) *OPTIMIZING GLOBAL CLINICAL TRIALS.*—Section
 21 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
 22 U.S.C. 360bbb–8a(b)) is amended—

23 (1) by striking “subsection” each place it ap-
 24 pears and inserting “paragraph”; and

1 (2) by inserting “an *in vitro* clinical test, as de-
 2 fined in paragraph (ss) of such section,” before “or a
 3 biological product”.

4 (g) *PATIENT PARTICIPATION IN MEDICAL PRODUCT*
 5 *DISCUSSION*.—The heading of subsection (a) of section
 6 569C of the Federal Food, Drug, and Cosmetic Act (21
 7 U.S.C. 360bbb–8c) is amended by striking “*DRUGS AND*
 8 *DEVICES*” and inserting “*DRUGS, DEVICES, AND IN VITRO*
 9 *CLINICAL TESTS*”.

10 (h) *REGULATIONS AND HEARINGS*.—Clause (ii) of sec-
 11 tion 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic
 12 Act (21 U.S.C. 371(h)(1)(C)) is amended—

13 (1) by inserting “and *in vitro* clinical tests”
 14 after “*devices*”; and

15 (2) by moving the margin of such clause 2 ems
 16 to the left.

17 (i) *RECORDS*.—Section 703 of the Federal Food, Drug,
 18 and Cosmetic Act (21 U.S.C. 373) is amended—

19 (1) by inserting “*in vitro* clinical tests,” after
 20 “*devices*,” each place such term appears; and

21 (2) by inserting “*in vitro* clinical test,” after
 22 “*device*,” each place such term appears.

23 (j) *FACTORY INSPECTION*.—Section 704 of the Federal
 24 Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other than
 25 subsection (g)) is amended—

1 (1) *by striking “drugs or devices” each place it*
 2 *appears and inserting “drugs, devices, or in vitro*
 3 *clinical tests”;*

4 (2) *in subsection (a)(1), in the fourth sentence,*
 5 *by striking “or chapter IX” and inserting “section*
 6 *587S, section 587M, section 587N, or chapter IX”;*

7 (3) *after making the amendments in paragraphs*
 8 *(1) and (2), by inserting “in vitro clinical tests,”*
 9 *after “devices,” each place it appears;*

10 (4) *in subsection (a)(2)(B)—*

11 (A) *by inserting “or in vitro clinical tests”*
 12 *after “prescribe or use devices”; and*

13 (B) *by inserting “or in vitro clinical tests”*
 14 *after “process devices”;*

15 (5) *by inserting “in vitro clinical test,” after*
 16 *“device,” each place it appears;*

17 (6) *in subsection (e), by inserting “, or section*
 18 *587M, 587N, or 587S,” after “section 519 or 520(g)”;*

19 (7) *in subsection (f)(3)—*

20 (A) *in subparagraph (A), by striking “or”*
 21 *at the end;*

22 (B) *in subparagraph (B), by striking the*
 23 *period at the end and inserting “; or”;* and

24 (C) *after subparagraph (B), by inserting*
 25 *the following:*

1 “(C) is accredited under section 587Q.”;

2 and

3 (8) by adding at the end the following:

4 “(i) For purposes of this section, the term ‘establish-
5 ment’ includes a laboratory performing an *in vitro* clinical
6 test.”.

7 (k) *PUBLICITY*.—Section 705(b) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by
9 inserting “*in vitro* clinical tests,” after “devices,”.

10 (l) *PRESUMPTION*.—Section 709 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
12 inserting “*in vitro* clinical test,” after “device,”.

13 (m) *LISTING AND CERTIFICATION OF COLOR ADDI-*
14 *TIVES FOR FOODS, DRUGS, AND COSMETICS*.—Section
15 721(a) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 379e(a)) is amended—

17 (1) in the matter preceding paragraph (1), by
18 inserting “or *in vitro* clinical tests” after “or de-
19 vices”; and

20 (2) in the flush text following paragraph (2)—

21 (A) by inserting “or an *in vitro* clinical
22 test” after “a device”; and

23 (B) by inserting “or *in vitro* clinical tests”
24 after “devices”.

1 *(n) IMPORTS AND EXPORTS.—Section 801 of the Fed-*
 2 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 381) is*
 3 *amended—*

4 *(1) in subsection (a)—*

5 *(A) by inserting “in vitro clinical tests,”*
 6 *after “devices,” each place it appears; and*

7 *(B) by inserting “in the case of an in vitro*
 8 *clinical test, the test does not conform to the ap-*
 9 *plicable requirements of section 587K, or” after*
 10 *“requirements of section 520(f), or”;*

11 *(2) in subsection (d)(3)—*

12 *(A) in subparagraph (A)—*

13 *(i) in the matter preceding clause (i),*
 14 *by inserting “and no component of an in*
 15 *vitro clinical test or other article of in vitro*
 16 *clinical test that requires further proc-*
 17 *essing,” after “health-related purposes”;*

18 *(ii) in clause (i), by striking “drug or*
 19 *device” and inserting “drug, device, or in*
 20 *vitro clinical test”;* and

21 *(iii) in clause (i)(I), by inserting “in*
 22 *vitro clinical test,” after “device,”; and*

23 *(B) in subparagraph (B), by inserting “in*
 24 *vitro clinical test,” after “device,”;*

1 (3) in subsection (e)(1), by inserting “in vitro
2 *clinical test*,” after “device,”; and

3 (4) in subsection (o)—

4 (A) by inserting “or in vitro clinical test”
5 after “device”; and

6 (B) by inserting “, or under section 587J of
7 each foreign establishment,” after “section 510(i)
8 of each establishment”.

9 (o) OFFICE OF INTERNATIONAL RELATIONS.—Section
10 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 383) is amended—

12 (1) in subsection (b)—

13 (A) in the matter preceding paragraph (1),
14 by inserting “and in vitro clinical tests” after
15 “devices”; and

16 (B) in paragraph (1), by striking “, and”
17 and inserting “and quality requirements estab-
18 lished under section 587K; and”; and

19 (2) in subsection (c)—

20 (A) in paragraph (2), by inserting “in vitro
21 clinical tests,” after “devices,”; and

22 (B) in paragraph (4), by inserting “or in
23 vitro clinical tests” after “devices”.

24 (p) RECOGNITION OF FOREIGN GOVERNMENT INSPEC-
25 TIONS.—Section 809(a)(1) of the Federal Food, Drug, and

1 *Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by insert-*
 2 *ing “, or of foreign establishments registered under section*
 3 *587J” after “510(h)”.*

4 (q) *FOOD AND DRUG ADMINISTRATION.—Section*
 5 *1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21*
 6 *U.S.C. 393(b)(2)) is amended—*

7 (1) *in subparagraph (D), by striking “and” at*
 8 *the end;*

9 (2) *in subparagraph (E), by striking the semi-*
 10 *colon at the end and inserting “; and”; and*

11 (3) *by adding at the end the following:*

12 “(F) *in vitro* clinical tests are analytically
 13 and clinically valid;”.

14 (r) *OFFICE OF WOMEN’S HEALTH.—Section 1011(b)*
 15 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 16 *399b(b)) is amended—*

17 (1) *in paragraph (1), by inserting “in vitro clin-*
 18 *ical tests,” after “devices,”; and*

19 (2) *in paragraph (4), by striking “and device*
 20 *manufacturers” and inserting “device manufacturers,*
 21 *and in vitro clinical test developers”.*

22 (s) *COUNTERMEASURE PROVISIONS OF THE PUBLIC*
 23 *HEALTH SERVICE ACT.—Title III of the Public Health*
 24 *Service Act is amended—*

1 (1) in section 319F-1(a)(2)(A) (42 U.S.C. 247d-
2 6a(a)(2)(A))—

3 (A) in the matter preceding clause (i)—

4 (i) by striking “or device” and insert-
5 ing “device”; and

6 (ii) by inserting “or an in vitro clin-
7 ical tests (as that term is defined in section
8 201(ss) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 321(ss))),” after “Act
10 (21 U.S.C. 321(h))),”; and

11 (B) in each of clauses (ii) and (iii), by
12 striking “or device” and inserting “device, or in
13 vitro clinical test”;

14 (2) in section 319F-2(c)(1)(B) (42 U.S.C. 247d-
15 6b(c)(1)(B))—

16 (A) by striking “or device” and inserting
17 “device”; and

18 (B) by inserting “, or an in vitro clinical
19 test (as that term is defined in section 201(ss) of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 321(ss)))” after “Act (21 U.S.C.
22 321(h))),”; and

23 (3) in section 319F-3(i)(7) (42 U.S.C. 247d-
24 6d(i)(7))—

1 (A) in the matter preceding subparagraph

2 (A)—

3 (i) by striking “or device” and insert-
4 ing “device”; and

5 (ii) by inserting “or an in vitro clin-
6 ical tests (as that term is defined in section
7 201(ss) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 321(ss)),” after “Act
9 (21 U.S.C. 321(h))”;

10 (B) in subparagraph (A)—

11 (i) by moving the margin of clause
12 (iii) 2 ems to the left; and

13 (ii) in clause (iii), by striking “or de-
14 vice” and inserting “device, or in vitro clin-
15 ical test”; and

16 (C) in subparagraph (B)—

17 (i) in clause (i), by inserting “or of-
18 fered under a technology certification order”
19 after “approved or cleared”; and

20 (ii) in clause (ii), by striking “or
21 520(g)” and inserting “, 520(g), or 587S”.

22 **SEC. 825. TRANSITION.**

23 (a) **IMPLEMENTATION.**—

24 (1) **EFFECTIVE DATE.**—

1 (A) *IN GENERAL.*—*Except as otherwise pro-*
 2 *vided in this section, the amendments made by*
 3 *this Act shall take effect on October 1, 2027 (in*
 4 *this section and in subchapter J of chapter V of*
 5 *the Federal Food, Drug, and Cosmetic Act, as*
 6 *added by this Act, referred to in this section as*
 7 *the “effective date of this Act”).*

8 (B) *EXCEPTIONS.*—

9 (i) *IN GENERAL.*—*The Secretary of*
 10 *Health and Human Services (in this section*
 11 *referred to as the “Secretary”) may take the*
 12 *actions described in paragraph (2), and*
 13 *may expend such funds as the Secretary de-*
 14 *termines necessary to ensure an orderly*
 15 *transition, including prior to the effect date*
 16 *of this Act.*

17 (ii) *IMPLEMENTATION OF CERTAIN*
 18 *PROVISIONS.*—*The Secretary may imple-*
 19 *ment sections 587J and 587U of the Federal*
 20 *Food, Drug, and Cosmetic Act (as added by*
 21 *section 823) beginning on October 1, 2024,*
 22 *and such sections may take effect not earlier*
 23 *than October 1, 2027, to the extent and for*
 24 *the purposes indicated in such sections. In*
 25 *the case of a developer who, between October*

1 1, 2024, and the effective date of this Act,
 2 registers under such section 587J with re-
 3 spect to an article that is an *in vitro* clin-
 4 ical test, such developer shall not be re-
 5 quired to register with respect to such arti-
 6 cle under section 510 of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 360).

8 (2) ACTIONS.—The Secretary—

9 (A) shall—

10 (i) within 1 year of the date of enact-
 11 ment of this Act, hold the public meetings
 12 described in section 587D(i) of the Federal
 13 Food, Drug, and Cosmetic Act (as added by
 14 section 823);

15 (ii) within 3 years of the date of enact-
 16 ment of this Act, promulgate final regula-
 17 tions required under the amendments made
 18 by this Act; and

19 (iii) within 30 months of the date of
 20 enactment of this Act, issue final guidance
 21 on applicability requirements under amend-
 22 ments made by this Act; and

23 (B) may take additional actions after the
 24 date of enactment that the Secretary determines

1 *necessary to ensure an orderly transition, in-*
2 *cluding—*

3 *(i) establishment of mitigating meas-*
4 *ures for an in vitro clinical test or category*
5 *of in vitro clinical tests, which may not*
6 *take effect until after the effective date de-*
7 *scribed in paragraph (1)(A); and*

8 *(ii) establishment of the comprehensive*
9 *test information system under section 587T*
10 *of the Federal Food, Drug, and Cosmetic*
11 *Act, as added by section 823.*

12 (3) *APPLICABILITY OF GUIDANCE AND REGULA-*
13 *TIONS.—Notwithstanding the date on which guidance*
14 *or regulations are issued under paragraph (2) and*
15 *section 587K of the Federal Food, Drug, and Cosmetic*
16 *Act, as added by section 823, no guidance or regula-*
17 *tions issued pursuant to the amendments made by*
18 *this Act shall be implemented or take effect until the*
19 *effective date of this Act, except as otherwise specified*
20 *in this Act (including the amendments made by this*
21 *Act).*

22 (b) *APPLICATION OF AUTHORITIES TO IN VITRO CLIN-*
23 *ICAL TESTS UNDER REVIEW ON THE EFFECTIVE DATE OF*
24 *THIS ACT.—For any in vitro clinical test for which a sub-*
25 *mission for approval under section 515 of the Federal Food,*

1 *Drug, and Cosmetic Act (21 U.S.C. 360e), clearance under*
 2 *section 510(k) of such Act (21 U.S.C. 360(k)), authorization*
 3 *under section 513(f)(2) of such Act (21 U.S.C. 360c(f)(2)),*
 4 *or licensure under section 351 of the Public Health Service*
 5 *Act (42 U.S.C. 262) is pending on the effective date of this*
 6 *Act, including transitional in vitro clinical tests as de-*
 7 *scribed in subsection (c), the Secretary may review and take*
 8 *action on such submission after the effective date of this*
 9 *Act according to the statutory provision under which such*
 10 *submission was submitted.*

11 *(c) APPLICATION OF AUTHORITIES TO TRANSITIONAL*
 12 *IN VITRO CLINICAL TESTS.—*

13 *(1) DEFINITION.—For purposes of this section,*
 14 *the term “transitional in vitro clinical test” means*
 15 *an in vitro clinical test that—*

16 *(A) is first offered for clinical use during*
 17 *the period beginning on the date of enactment of*
 18 *this Act and ending on the effective date of this*
 19 *Act;*

20 *(B) is developed by a clinical laboratory*
 21 *certified by the Secretary under section 353 of*
 22 *the Public Health Service Act (42 U.S.C. 263a)*
 23 *that meets the requirements for performing high-*
 24 *complexity testing and performed—*

1 (i) *in the same clinical laboratory in*
2 *which the test was developed and for which*
3 *a certification is still in effect under such*
4 *section 353 that meets the requirements to*
5 *perform tests of high complexity;*

6 (ii) *by another laboratory for which a*
7 *certificate is in effect under such section 353*
8 *that meets the requirements to perform tests*
9 *of high complexity, is within the same cor-*
10 *porate organization, and has common own-*
11 *ership by the same parent corporation as*
12 *the laboratory in which the test was devel-*
13 *oped; or*

14 (iii) *in the case of a test that was de-*
15 *veloped by the Centers for Disease Control*
16 *and Prevention or another laboratory in a*
17 *public health laboratory network coordi-*
18 *nated or managed by the Centers for Dis-*
19 *ease Control and Prevention, by a clinical*
20 *laboratory for which a certificate is in effect*
21 *under such section 353 that meets the re-*
22 *quirements to perform tests of high com-*
23 *plexity, and that is within a public health*
24 *laboratory network coordinated or managed*

by the Centers for Disease Control and Prevention; and

(C) when first offered, is not approved under section 515 of the Federal Food, Drug, and Cosmetic Act, cleared under section 510(k) of such Act, authorized under section 513(f)(2) of such Act, subject to a humanitarian device exemption under section 520(m) of such Act (21 U.S.C. 360j(m)), subject to an exemption for investigation use under section 520(g) of such Act (21 U.S.C. 360j(g)), authorized under section 564 of such Act (21 U.S.C. 360bbb-3), or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) *PREMARKET REVIEW OR TECHNOLOGY CERTIFICATION.*—A transitional in vitro clinical test that is the subject of an application for premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act or technology certification application under section 587D of such Act, as added by this Act, may continue to be offered, sold, or distributed without marketing authorization until completion of the Secretary's review of the premarket application or technology certification application, if such applica-

tion is submitted no later than 90 days after the effective date of this Act.

(3) *TESTS APPROVED BY NEW YORK STATE.*—
Notwithstanding paragraph (2), a transitional in vitro clinical test that has been approved by the New York State Department of Health may continue to be offered, sold, or distributed after the effective date if—

(A) starting on the effective date of this Act, the in vitro clinical test complies with the requirements of subchapter J of the Federal Food, Drug, and Cosmetic Act, as added by this Act, except for section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 823, and design control provisions of section 587K of such Act;

(B) each test report template for the test bears a statement of adequate prominence that reads as follows: “This in vitro clinical test was developed and first introduced prior to the effective date of the VALID Act of 2022. This test was approved by the New York State Department of Health, but the test has not been reviewed by the Food and Drug Administration.”;

(C) a premarket application under section 587B of the Federal Food, Drug, and Cosmetic

1 *Act, as added by section 823, or technology cer-*
 2 *tification application under section 587D of such*
 3 *Act, as added by section 823, is submitted no*
 4 *later than—*

5 *(i) 5 years after the effective date of*
 6 *this Act, if the in vitro clinical test is ap-*
 7 *proved by the New York State Department*
 8 *of Health as a genetic testing molecular test,*
 9 *a microbiology molecular test, an oncology*
 10 *molecular test, or any other type of molec-*
 11 *ular test; or*

12 *(ii) 2 years after the effective date of*
 13 *this Act, if the in vitro clinical test is ap-*
 14 *proved by the New York State Department*
 15 *of Health as a type of test not described in*
 16 *clause (i); and*

17 *(D) a test in compliance with this para-*
 18 *graph may continue to be offered, sold, or dis-*
 19 *tributed until the completion of the Secretary's*
 20 *review of the premarket application or tech-*
 21 *nology certification application described in sub-*
 22 *paragraph (C).*

23 *(d) CONVERSION.—*

24 *(1) DEEMED PREMARKET APPROVAL.—Begin-*
 25 *ning on the effective date of this Act—*

1 (A) any *in vitro* clinical test with a pre-
 2 market approval under section 515 of the Fed-
 3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 4 360e) or a licensure under section 351 of the
 5 Public Health Service Act (42 U.S.C. 262) is
 6 deemed to be approved pursuant to an applica-
 7 tion under section 587B(a) of the Federal Food,
 8 Drug, and Cosmetic Act, as added by this Act;
 9 and

10 (B) any *in vitro* clinical test (as so defined)
 11 that was cleared under section 510(k) of the Fed-
 12 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 13 360(k)) or authorized under section 513(f)(2) of
 14 the Federal Food, Drug, and Cosmetic Act (21
 15 U.S.C. 360c(f)(2)) is deemed to be approved pur-
 16 suant to an application under section 587B(b) of
 17 the Federal Food, Drug, and Cosmetic Act, as
 18 added by this Act.

19 (2) *DEEMED INVESTIGATIONAL USE EXEMP-*
 20 *TION.*—Any *in vitro* clinical test that has an inves-
 21 tigational device exemption in effect under section
 22 520(g) of the Federal Food, Drug, and Cosmetic Act
 23 (21 U.S.C. 360j(g)) is deemed to have an investiga-
 24 tional use exemption in effect under section 587S of

1 *such Act, as added by this Act, beginning on the effec-*
2 *tive date of this Act.*

3 (3) *DEEMED HUMANITARIAN DEVICE EXEMP-*
4 *TION.—Any in vitro clinical test that has an ap-*
5 *proved humanitarian device exemption under section*
6 *520(m) of such Act is deemed to have a humanitarian*
7 *test exemption under section 587A(g) of such Act, as*
8 *added by this Act, beginning on the effective date of*
9 *this Act.*

10 (4) *DEEMED DESIGNATED BREAKTHROUGH.—*
11 *Any in vitro clinical test that has received a break-*
12 *through device designation under section*
13 *515B(e)(1)(D) of such Act (21 U.S.C. 360e–*
14 *3(e)(1)(D)) is deemed to have a breakthrough in vitro*
15 *clinical test designation under section 587C of such*
16 *Act, as added by this Act, beginning on the effective*
17 *date of this Act.*

18 (5) *DEEMED REQUEST FOR INFORMAL FEED-*
19 *BACK.—With regard to any in vitro clinical test that*
20 *is the subject of a pre-submission request described in*
21 *the guidance, “Requests for Feedback and Meetings for*
22 *Medical Device Submissions: The Q-Submission Pro-*
23 *gram”, issued by the Food and Drug Administration*
24 *on January 6, 2021, such request is deemed to con-*
25 *stitute a request for informal feedback under section*

1 587F of the Federal Food, Drug, and Cosmetic Act,
2 as added by section 823, beginning on the effective
3 date of this Act.

4 (e) *PREVIOUSLY CLASSIFIED DEVICES.*—Notwith-
5 standing section 587 of the Federal Food, Drug, and Cos-
6 metic Act, as added by section 823, for purposes of sub-
7 chapter J of chapter V of such Act, as added by section
8 823, the following apply:

9 (1) *In the case of an in vitro clinical test type*
10 *that has been classified by the Secretary as a class I*
11 *device pursuant to section 513 of such Act (21 U.S.C.*
12 *360c), such in vitro clinical test shall be low-risk, un-*
13 *less the in vitro clinical test is a test described in sec-*
14 *tion 510(l) of such Act or the test is redesignated by*
15 *the Secretary pursuant to section 587F of such Act.*

16 (2) *In the case of an in vitro clinical test type*
17 *that has been classified by the Secretary as a class II*
18 *device pursuant to section 513 of such Act (21 U.S.C.*
19 *360c), such in vitro clinical test shall be moderate-*
20 *risk, unless inaccurate results from the test would be*
21 *immediately life threatening or the test is redesign-*
22 *ated by the Secretary pursuant to section 587F of*
23 *such Act.*

24 (3) *In the case of an in vitro clinical test type*
25 *that has been classified by the Secretary as a class III*

1 *device pursuant to section 513 of such Act (21 U.S.C.*
 2 *360c) or an in vitro clinical test licensed pursuant to*
 3 *section 351 of the Public Health Service Act (42*
 4 *U.S.C. 262), such in vitro clinical test shall be high-*
 5 *risk, unless redesignated by the Secretary pursuant to*
 6 *section 587F of the Federal Food, Drug, and Cosmetic*
 7 *Act.*

8 **SEC. 826. EMERGENCY USE AUTHORIZATION.**

9 *(a) IN GENERAL.—Section 564 of the Federal Food,*
 10 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-*
 11 *ed—*

12 *(1) by inserting “or developer” after “manufac-*
 13 *turer”, each place such term appears;*

14 *(2) in subsection (a)—*

15 *(A) in paragraphs (1) and (4)(C), by in-*
 16 *serting “in vitro clinical test,” before “or biological*
 17 *product” each place such term appears;*

18 *(B) in paragraph (2)(A), by striking “or*
 19 *515” and inserting “515, or 587B”; and*

20 *(C) by adding at the end the following:*

21 *“(F) The terms ‘develop’ and ‘developer’,*
 22 *with respect to an in vitro clinical test, have the*
 23 *meanings given such terms in section 587.”;*

24 *(3) in subsection (b), by inserting “or developer”*
 25 *after “manufacturer” each place such term appears;*

1 (4) in subsection (e)—

2 (A) by inserting “or developers” after
3 “manufacturers” each place such term appears;

4 (B) in paragraph (2)(B)(ii), by inserting
5 “or develop” after “not manufacture”;

6 (C) in paragraph (3)—

7 (i) in subparagraph (A), by striking
8 “or 520(f)(1)” and inserting “, 520(f)(1), or
9 587V”;

10 (ii) in subparagraph (B), by striking
11 “and” at the end;

12 (iii) in subparagraph (C), by striking
13 the period and inserting “ or 587O; and”;
14 and

15 (iv) by adding at the end the following:
16 “(D) quality requirements (with respect to
17 in vitro clinical tests) under section 587K.”; and

18 (D) in paragraph (4)—

19 (i) in subparagraph (A), by striking “;
20 or” and inserting a semicolon;

21 (ii) in subparagraph (B), by striking
22 the period and inserting “; or”; and

23 (iii) by adding at the end the fol-
24 lowing:

1 “(C) *with respect to in vitro clinical tests,*
 2 *requirements applicable to restricted in vitro*
 3 *clinical tests pursuant to section 587O.*”;

4 (5) *in subsection (k), by striking “or 520(g)”*
 5 *and inserting “520(g), or 587S”; and*

6 (6) *in subsection (m)—*

7 (A) *in the subsection heading, by striking*
 8 *“LABORATORY TESTS ASSOCIATED WITH DE-*
 9 *VICES” inserting “IN VITRO CLINICAL TESTS”*
 10 *after “DEVICES”; and*

11 (B) *in paragraph (1)—*

12 (i) *by striking “to a device” and in-*
 13 *serting “to an in vitro clinical test”; and*

14 (ii) *by striking “such device” and in-*
 15 *serting “such in vitro clinical test”.*

16 (b) *EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-*
 17 *tion 564A of the Federal Food, Drug, and Cosmetic Act (21*
 18 *U.S.C. 360bbb–3a) is amended—*

19 (1) *in subsection (a)—*

20 (A) *in paragraph (2), by inserting “in vitro*
 21 *clinical test,” after “device,”; and*

22 (B) *by adding at the end the following:*

23 “(3) *DEVELOPER.—The term ‘developer’, with*
 24 *respect to an in vitro clinical test, has the meaning*
 25 *given such term in section 587.*”;

1 (2) by inserting “or developer” after “manufac-
2 turer” each place it appears; and

3 (3) in subsection (c)(1)—

4 (A) by inserting “or quality requirements”
5 after “good manufacturing practice require-
6 ments”; and

7 (B) by striking “or 520(f)(1)” and inserting
8 “, 520(f)(1), or 587K”.

9 (c) *PRODUCTS HELD FOR EMERGENCY USE.*—Section
10 564B(2) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 360bbb–3b(2)) is amended—

12 (1) in subparagraph (A), by striking “or 515”
13 and inserting “515, or 587B”; and

14 (2) in subparagraph (B), by striking “or 520”
15 and inserting 520, or 587S.

16 **SEC. 827. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

17 Section 511A of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 360a–2) is amended—

19 (1) in subsection (a)(1)(C)—

20 (A) by striking “clear under section 510(k),
21 classify under section 513(f)(2), or approve
22 under section 515” and inserting “approve
23 under section 587B, exempt from premarket re-
24 view under section 587C, or grant a technology
25 certification order under section 587D”; and

1 (B) by striking “testing devices” and insert-
 2 ing “in vitro clinical tests”;

3 (2) in subsection (c)(5)—

4 (A) by striking “drug or device” and insert-
 5 ing “drug, device, or in vitro clinical test”; and

6 (B) by striking “the drug or the device” and
 7 inserting “the drug, device, or in vitro clinical
 8 test”;

9 (3) in subsection (e)—

10 (A) in the heading, by striking “TESTING
 11 DEVICES” and inserting “IN VITRO CLINICAL
 12 TESTS”;

13 (B) in paragraph (1)—

14 (i) by striking “510, 513, and 515,”
 15 and inserting “587B, and 587D”;

16 (ii) by striking “antimicrobial suscep-
 17 tibility testing device” and inserting “anti-
 18 microbial susceptibility in vitro clinical
 19 test”; and

20 (iii) by striking “such device” and in-
 21 serting “such in vitro clinical test”; and

22 (C) in paragraph (2)—

23 (i) in the heading, by striking “TEST-
 24 ING DEVICES” and inserting “IN VITRO
 25 CLINICAL TESTS”;

1 (ii) in subparagraphs (A) and (B)
 2 (other than clause (iii) of such subpara-
 3 graph (B)), by striking “device” each place
 4 it appears and inserting “in vitro clinical
 5 test”;

6 (iii) in subparagraph (B)(iii), by
 7 striking “a device” and inserting “an in
 8 vitro clinical test”; and

9 (iv) by amending subparagraph (C) to
 10 read as follows:

11 “(C) The antimicrobial susceptibility in
 12 vitro clinical test meets all other requirements to
 13 be approved under section 587B, to be exempted
 14 from premarket review under section 587C, or to
 15 be offered under a technology certification order
 16 under section 587D.”;

17 (4) in subsection (f), by amending paragraph (1)
 18 to read as follows:

19 “(1) The term ‘antimicrobial susceptibility in
 20 vitro clinical test’ means an in vitro clinical test that
 21 utilizes susceptibility test interpretive criteria to de-
 22 termine and report the in vitro susceptibility of cer-
 23 tain microorganisms to a drug (or drugs).”; and

24 (5) in subsection (g)(2)—

1 (A) by amending the matter preceding sub-
2 paragraph (A) to read as follows:

3 “(2) with respect to approving an application
4 under section 587B or granting a technology certifi-
5 cation order under section 587D—”; and

6 (B) in subparagraph (A)—

7 (i) by striking “device” and inserting
8 “in vitro clinical test”; and

9 (ii) by striking “antimicrobial suscep-
10 tibility testing device” and inserting “anti-
11 microbial susceptibility in vitro clinical
12 test”.

13 **SEC. 828. COMBINATION PRODUCTS.**

14 (a) *IN GENERAL.*—Section 503(g) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

16 (1) in paragraph (1)—

17 (A) in subparagraph (A), by striking “or
18 biological product” and inserting “in vitro clin-
19 ical test, or biological product (except for a prod-
20 uct constituted of a device and an in vitro clin-
21 ical test)”;

22 (B) in subparagraph (B), by adding at the
23 end the following: “For purposes of this Act, a
24 product that constitutes a combination of a de-
25 vice and an in vitro clinical test is not a com-

1 *ination product within the meaning of this sub-*
 2 *section.”; and*

3 *(C) in subparagraph (D)(ii)—*

4 *(i) by inserting “or in vitro clinical*
 5 *test” after “device”; and*

6 *(ii) by inserting “and in vitro clinical*
 7 *tests” before “shall”;*

8 *(2) in paragraph (3), by striking “safety and ef-*
 9 *fectiveness or substantial equivalence” and inserting*
 10 *“safety and effectiveness, substantial equivalence, or*
 11 *analytical validity and clinical validity” before “for*
 12 *the approved constituent part”;*

13 *(3) in paragraph (4)—*

14 *(A) in subparagraph (A), by striking “or*
 15 *513(f)(2) (submitted in accordance with para-*
 16 *graph (5))” and inserting “513(f)(2) (submitted*
 17 *in accordance with paragraph (5)), 587B, or*
 18 *587D, or an exempt test under section 587C, as*
 19 *applicable”; and*

20 *(B) in subparagraph (B), by inserting “,*
 21 *587B, or 587D” after “section 515”;*

22 *(4) in paragraph (5)(A), by striking “or 510(k)”*
 23 *and inserting “, 510(k), 587B, or 587D”;*

1 (5) in paragraph (7), by striking “or substantial
2 equivalence” and inserting “, substantial equivalence,
3 or analytical validity and clinical validity”;

4 (6) in paragraph (8), by adding at the end the
5 following:

6 “(I) This paragraph shall not apply to a
7 product constituted of a device and an in vitro
8 clinical test.”; and

9 (7) in paragraph (9)—

10 (A) in subparagraph (C)(i), by striking “or
11 520(g)” and inserting “520(g), 587B, or 587D”;
12 and

13 (B) in subparagraph (D), by striking “or
14 520” and inserting “520, 587B, or 587D”.

15 (b) *CLASSIFICATION OF PRODUCTS.*—Section 563 of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360bbb–2) is amended by adding at the end the following:

18 “(d) *EXEMPTION.*—This section shall not apply to a
19 product constituted of a device and an in vitro clinical
20 test.”.

21 **SEC. 829. RESOURCES.**

22 (a) *FINDINGS.*—Congress finds that the fees authorized
23 by this section will be dedicated to meeting the goals identi-
24 fied in the letters from the Secretary of Health and Human
25 Services to the Committee on Health, Education, Labor,

1 *and Pensions of the Senate and the Committee on Energy*
 2 *and Commerce of the House of Representatives, as set forth*
 3 *in the Congressional Record.*

4 *(b) ESTABLISHMENT OF USER FEE PROGRAM.—*

5 *(1) DEVELOPMENT OF USER FEES FOR IN VITRO*
 6 *CLINICAL TESTS.—*

7 *(A) IN GENERAL.—Beginning not later than*
 8 *October 1, 2025, the Secretary of Health and*
 9 *Human Services (in this section referred to as*
 10 *the “Secretary”) shall develop recommendations*
 11 *to present to Congress with respect to the goals,*
 12 *and plans for meeting the goals, for the process*
 13 *for the review of in vitro clinical test submis-*
 14 *sions and applications under subchapter J of*
 15 *chapter V of the Federal Food, Drug, and Cos-*
 16 *metic Act, as added by this Act, for the first 5*
 17 *fiscal years after fiscal year 2027 and for the au-*
 18 *thorization of the In Vitro Clinical Test User Fee*
 19 *Program, as described in this section, for such*
 20 *fiscal years. In developing such recommenda-*
 21 *tions, the Secretary shall consult with—*

22 *(i) the Committee on Health, Edu-*
 23 *cation, Labor, and Pensions of the Senate;*

24 *(ii) the Committee on Energy and*
 25 *Commerce of the House of Representatives;*

- 1 (iii) scientific and academic experts;
- 2 (iv) health care professionals;
- 3 (v) representatives of patient and con-
- 4 sumer advocacy groups; and
- 5 (vi) the regulated industry.

6 (B) *PRIOR PUBLIC INPUT.*—Prior to begin-
7 ning negotiations with the regulated industry on
8 the authorization of the *In Vitro Clinical Test*
9 *User Fee Program*, as described in this section,
10 the Secretary shall—

11 (i) publish a notice in the *Federal Reg-*
12 ister requesting public input on the author-
13 ization of user fees;

14 (ii) hold a public meeting at which the
15 public may present its views on the author-
16 ization, including specific suggestions for
17 the recommendations submitted under sub-
18 paragraph (E);

19 (iii) provide a period of 30 days after
20 the public meeting to obtain written com-
21 ments from the public suggesting changes to
22 the authorization of the *In Vitro Clinical*
23 *Test User Fee Program*, as described in this
24 section; and

1 (iv) publish any comments received
2 under clause (iii) on the website of the Food
3 and Drug Administration.

4 (C) *PERIODIC CONSULTATION*.—Not less fre-
5 quently than once every month during negotia-
6 tions with the regulated industry, the Secretary
7 shall hold discussions with representatives of pa-
8 tient and consumer advocacy groups to continue
9 discussions of the authorization of the In Vitro
10 Clinical Test User Fee Program and to solicit
11 suggestions to be included in the recommenda-
12 tions transmitted to Congress under subpara-
13 graph (E).

14 (D) *PUBLIC REVIEW OF RECOMMENDA-*
15 *TIONS*.—After negotiations with the regulated in-
16 dustry, the Secretary shall—

17 (i) present the recommendations devel-
18 oped under subparagraph (A) to the Com-
19 mittee on Health, Education, Labor, and
20 Pensions of the Senate and the Committee
21 on Energy and Commerce of the House of
22 Representatives;

23 (ii) publish such recommendations in
24 the Federal Register;

1 (iii) provide for a period of 30 days for
 2 the public to provide written comments on
 3 such recommendations;

4 (iv) hold a meeting at which the public
 5 may present its views on such recommenda-
 6 tions; and

7 (v) after consideration of such public
 8 views and comments, revise such rec-
 9 ommendations as necessary.

10 (E) TRANSMITTAL OF RECOMMENDA-
 11 TIONS.—

12 (i) IN GENERAL.—Not later than Jan-
 13 uary 15, 2027, the Secretary shall transmit
 14 to Congress the revised recommendations
 15 under subparagraph (A), a summary of the
 16 views and comments received under such
 17 subparagraph, and any changes made to the
 18 recommendations in response to such views
 19 and comments.

20 (ii) RECOMMENDATION REQUIRE-
 21 MENTS.—The recommendations transmitted
 22 under this subparagraph shall—

23 (I) include the number of full-time
 24 equivalent employees per fiscal year
 25 that are agreed to be hired to carry out

1 the goals included in such rec-
2 ommendations for each year of the 5-
3 year period;

4 (II) provide that the amount of
5 operating reserve balance in the user
6 fee program established under this sec-
7 tion is not more than the equivalent of
8 10 weeks of operating reserve;

9 (III) require the development of a
10 strategic plan for any surplus within
11 the operating reserve account above the
12 10-week operating reserve within 2
13 years of the establishment of the pro-
14 gram;

15 (IV) include an operating reserve
16 adjustment such that, if the Secretary
17 has an operating reserve balance in ex-
18 cess of 10 weeks of such operating re-
19 serves, the Secretary shall decrease such
20 fee revenue and fees to provide for not
21 more than 10 weeks of such operating
22 reserves;

23 (V) if an adjustment is made as
24 described in subclause (IV), provide the
25 rationale for the amount of the de-

1 crease in fee revenue and fees shall be
2 contained in the Federal Register; and
3 (VI) provide that the fees assessed
4 and collected for the full-time equivalent
5 employees at the Center for De-
6 vices and Radiological Health, with re-
7 spect to which the majority of time re-
8 porting data indicates are dedicated to
9 the process for the review of in vitro
10 clinical test submissions and applica-
11 tions under paragraph (5), are not
12 supported by the funds authorized to be
13 collected and assessed under section
14 738 of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 379j).

16 (F) PUBLICATION OF RECOMMENDATIONS.—

17 The Secretary shall publish on the website of the
18 Food and Drug Administration the revised rec-
19 ommendations under subparagraph (A), a sum-
20 mary of the views and comments received under
21 subparagraphs (B) through (D), and any
22 changes made to the recommendations originally
23 proposed by the Secretary in response to such
24 views and comments.

1 (G) MINUTES OF NEGOTIATION MEET-
2 INGS.—

3 (i) PUBLIC AVAILABILITY.—*The Sec-*
4 *retary shall make publicly available, on the*
5 *website of the Food and Drug Administra-*
6 *tion, minutes of all negotiation meetings*
7 *conducted under this subsection between the*
8 *Food and Drug Administration and the reg-*
9 *ulated industry not later than 30 days after*
10 *such meeting.*

11 (ii) CONTENT.—*The minutes described*
12 *under clause (i) shall summarize any sub-*
13 *stantive proposal made by any party to the*
14 *negotiations, any significant controversies*
15 *or differences of opinion during the negotia-*
16 *tions, and the resolution of any such con-*
17 *troversy or difference of opinion.*

18 (2) ESTABLISHMENT OF USER FEE PROGRAM.—
19 *Effective on October 1, 2027, provided that the Sec-*
20 *retary transmits the recommendations under para-*
21 *graph (1)(E), the Secretary is authorized to collect*
22 *user fees relating to the review of in vitro clinical test*
23 *submissions and applications submitted under sub-*
24 *chapter J of chapter V of the Federal Food, Drug, and*
25 *Cosmetic Act, as added by this Act. Fees under such*

1 *program shall be assessed and collected only if the re-*
2 *quirements under paragraph (4) are met.*

3 (3) *AUDIT.—*

4 (A) *IN GENERAL.—On the date that is 2*
5 *years after first receiving a user fee applicable to*
6 *submission of an in vitro clinical test applica-*
7 *tion submitted under subchapter J of chapter V*
8 *of the Federal Food, Drug, and Cosmetic Act, as*
9 *added by this Act, and on a biennial basis there-*
10 *after, the Secretary shall perform an audit of the*
11 *costs of reviewing such applications under such*
12 *subchapter J. Such an audit shall compare the*
13 *costs of reviewing such applications under such*
14 *subchapter J to the amount of the user fee appli-*
15 *cable to such applications.*

16 (B) *ALTERATION OF USER FEE.—If the*
17 *audit performed under subparagraph (A) indi-*
18 *cates that the user fees applicable to applications*
19 *submitted under such subchapter J exceed 49*
20 *percent of the costs of reviewing such applica-*
21 *tions, the Secretary shall alter the user fees ap-*
22 *plicable to applications submitted under such*
23 *subchapter J such that the user fees do not exceed*
24 *such percentage.*

1 (C) *ACCOUNTING STANDARDS.*—*The Sec-*
 2 *retary shall perform an audit under subpara-*
 3 *graph (A) in conformance with the accounting*
 4 *principles, standards, and requirements pre-*
 5 *scribed by the Comptroller General of the United*
 6 *States under section 3511 of title 31, United*
 7 *States Code, to ensure the validity of any poten-*
 8 *tial variability.*

9 (4) *CONDITIONS.*—*The user fee program de-*
 10 *scribed in this subsection shall take effect only if the*
 11 *Food and Drug Administration issues draft guidance*
 12 *related to the review requirements for in vitro diag-*
 13 *nostic tests that would be subject to premarket review*
 14 *under section 587B of the Federal Food, Drug, and*
 15 *Cosmetic Act, as added by section 823, the review re-*
 16 *quirements for test categories eligible for technology*
 17 *certification under section 587D of such Act, as added*
 18 *by section 823, and the parameters for the test cat-*
 19 *egories that would be exempt from any review under*
 20 *subchapter J of chapter V of such Act.*

21 (5) *USER FEE PROGRAM DEFINITIONS AND RE-*
 22 *SOURCE REQUIREMENTS.*—

23 (A) *IN GENERAL.*—*The term “process for*
 24 *the review of in vitro clinical test submissions*
 25 *and applications” means the following activities*

1 *of the Secretary with respect to the review of in*
2 *vitro clinical test premarket and technology cer-*
3 *tification applications including supplements for*
4 *such applications:*

5 *(i) The activities necessary for the re-*
6 *view of premarket applications, premarket*
7 *reports, technology certification applica-*
8 *tions, and supplements to such applications.*

9 *(ii) Actions related to submissions in*
10 *connection with in vitro clinical test devel-*
11 *opment, the issuance of action letters that*
12 *allow the marketing of in vitro clinical tests*
13 *or which set forth in detail the specific defi-*
14 *ciencies in such applications, reports, sup-*
15 *plements, or submissions and, where appro-*
16 *priate, the actions necessary to support the*
17 *development of in vitro clinical tests.*

18 *(iii) The inspection of manufacturing*
19 *establishments and other facilities under-*
20 *taken as part of the Secretary's review of*
21 *pending premarket applications, technology*
22 *certifications, and supplements.*

23 *(iv) Monitoring of research conducted*
24 *in connection with the review of such appli-*
25 *cations, supplements, and submissions.*

1 (v) *Review of in vitro clinical test ap-*
2 *plications subject to section 351 of the Pub-*
3 *lic Health Service Act (42 U.S.C. 262) and*
4 *activities conducted in anticipation of the*
5 *submission of such applications for inves-*
6 *tigational use under section 587S of the*
7 *Federal Food, Drug, and Cosmetic Act (as*
8 *added by section 823).*

9 (vi) *The development of guidance, pol-*
10 *icy documents, or regulations to improve*
11 *the process for the review of premarket ap-*
12 *plications, technology certification applica-*
13 *tions, and supplements.*

14 (vii) *The development of voluntary test*
15 *methods, consensus standards, or manda-*
16 *tory performance standards in connection*
17 *with the review of such applications, sup-*
18 *plements, or submissions and related activi-*
19 *ties.*

20 (viii) *The provision of technical assist-*
21 *ance to in vitro clinical test developers in*
22 *connection with the submission of such ap-*
23 *plications, reports, supplements, or submis-*
24 *sions.*

1 *(ix) Any activity undertaken in con-*
2 *nection with the initial classification or re-*
3 *classification of an in vitro clinical test in*
4 *connection with any requirement for ap-*
5 *proval or eligibility for an exemption from*
6 *premarket review of an in vitro clinical*
7 *test.*

8 *(x) Any activity undertaken in connec-*
9 *tion with making a pathway determination*
10 *of an in vitro clinical test, including the*
11 *identification, establishment, and imple-*
12 *mentation of mitigation measures.*

13 *(xi) Evaluation of postmarket studies*
14 *required as a condition of an approval of a*
15 *premarket application of an in vitro clin-*
16 *ical test and ensuring such studies are con-*
17 *ducted as required.*

18 *(xii) Any activity undertaken in con-*
19 *nection with ensuring in vitro clinical tests*
20 *marketed under an exemption from pre-*
21 *market review pursuant to section 587C or*
22 *587G meet the criteria for such exemption*
23 *and the applicable standard.*

24 *(xiii) Compiling, developing, and re-*
25 *viewing information on in vitro clinical*

1 *tests necessary to identify issues with the*
 2 *ability of in vitro clinical tests to meet the*
 3 *applicable standard, as applicable.*

4 *(B) RESOURCE REQUIREMENTS.—Fees col-*
 5 *lected and assessed under this section shall be*
 6 *used for the process for the review of in vitro*
 7 *clinical test applications, as described in sub-*
 8 *paragraph (A), and shall—*

9 *(i) be subject to the limitation under*
 10 *section 738(g)(3) of the Federal Food, Drug,*
 11 *and Cosmetic Act (21 U.S.C. 379j(g)(3)), in*
 12 *the same manner that fees collected and as-*
 13 *essed under section 737(9)(C) of such Act*
 14 *(21 U.S.C. 379i(9)(C)) are subject to such*
 15 *limitation;*

16 *(ii) include travel expenses for officers*
 17 *and employees of the Food and Drug Ad-*
 18 *ministration only if the Secretary deter-*
 19 *mines that such travel is directly related to*
 20 *an activity described in subparagraph (A);*
 21 *and*

22 *(iii) not be allocated to purposes de-*
 23 *scribed under section 722(a) of the Consoli-*
 24 *dated Appropriations Act, 2018 (Public*
 25 *Law 115–141).*

1 (c) *REPORTS.*—

2 (1) *PERFORMANCE REPORT.*—

3 (A) *IN GENERAL.*—

4 (i) *GENERAL REQUIREMENTS.*—*Begin-*
5 *ning with fiscal year 2028, for each fiscal*
6 *year for which fees are collected under this*
7 *section, the Secretary shall prepare and sub-*
8 *mit to the Committee on Health, Education,*
9 *Labor, and Pensions of the Senate and the*
10 *Committee on Energy and Commerce of the*
11 *House of Representatives annual reports*
12 *concerning the progress of the Food and*
13 *Drug Administration in achieving the goals*
14 *identified in the recommendations trans-*
15 *mitted to Congress by the Secretary pursu-*
16 *ant to subsection (b)(1)(E) during such fis-*
17 *cal year and the future plans of the Food*
18 *and Drug Administration for meeting the*
19 *goals.*

20 (ii) *ADDITIONAL INFORMATION.*—*Be-*
21 *ginning with fiscal year 2028, the annual*
22 *report under this subparagraph shall in-*
23 *clude the progress of the Food and Drug Ad-*
24 *ministration in achieving the goals, and fu-*

1 *ture plans for meeting the goals, includ-*
2 *ing—*

3 *(I) the number of premarket ap-*
4 *plications filed under section 587B of*
5 *the Federal Food, Drug, and Cosmetic*
6 *Act during the applicable fiscal year;*

7 *(II) the number of technology cer-*
8 *tification applications submitted under*
9 *section 587D of the Federal Food,*
10 *Drug, and Cosmetic Act during the ap-*
11 *plicable fiscal year for each review di-*
12 *vision;*

13 *(III) the number of breakthrough*
14 *designations under section 587I of the*
15 *Federal Food, Drug, and Cosmetic Act*
16 *during the applicable fiscal year; and*

17 *(IV) the number of information*
18 *requests requested by the Secretary*
19 *pursuant to section 587G(d) of such*
20 *Act.*

21 *(iii) REAL-TIME REPORTING.—*

22 *(I) IN GENERAL.—Not later than*
23 *30 calendar days after the end of the*
24 *second quarter of fiscal year 2028, and*
25 *not later than 30 calendar days after*

1 *the end of each quarter of each fiscal*
2 *year thereafter, the Secretary shall post*
3 *the data described in subclause (II) on*
4 *the website of the Food and Drug Ad-*
5 *ministration for such quarter and on a*
6 *cumulative basis for such fiscal year,*
7 *and may remove duplicative data from*
8 *the annual report under this subpara-*
9 *graph.*

10 *(II) DATA.—The Secretary shall*
11 *post the following data in accordance*
12 *with subclause (I):*

13 *(aa) The number and titles*
14 *of draft and final regulations on*
15 *topics related to the process for the*
16 *review of in vitro clinical test sub-*
17 *missions and applications, and*
18 *whether such regulations were re-*
19 *quired by statute or pursuant to*
20 *the recommendations transmitted*
21 *to Congress by the Secretary pur-*
22 *suant to subsection (b)(1)(E).*

23 *(bb) The number and titles of*
24 *draft and final guidance on topics*
25 *related to the process for the re-*

1 view of in vitro clinical test sub-
2 missions and applications, and
3 whether such guidances were
4 issued as required by statute or
5 pursuant to the recommendations
6 transmitted to Congress by the
7 Secretary pursuant to subsection
8 (b)(1)(E).

9 (cc) The number and titles of
10 public meetings held on topics re-
11 lated to the process for the review
12 of in vitro clinical tests, and if
13 such meetings were required by
14 statute or pursuant to the rec-
15 ommendations transmitted to
16 Congress by the Secretary pursu-
17 ant to subsection (b)(1)(E).

18 (iv) *RATIONALE FOR IVCT USER FEE*
19 *PROGRAM CHANGES.*—Beginning with fiscal
20 year 2028, the Secretary shall include in
21 the annual performance report under para-
22 graph (1)—

23 (I) data, analysis, and discussion
24 of the changes in the number of full-
25 time equivalents hired as agreed upon

1 *in the recommendations transmitted to*
2 *Congress by the Secretary pursuant to*
3 *subsection (b)(1)(E) and the number of*
4 *full-time equivalents funded by budget*
5 *authority at the Food and Drug Ad-*
6 *ministration by each division within*
7 *the Center for Devices and Radio-*
8 *logical Health, the Center for Biologics*
9 *Evaluation and Research, the Office of*
10 *Regulatory Affairs, and the Office of*
11 *the Commissioner;*

12 *(II) data, analysis, and discussion*
13 *of the changes in the fee revenue*
14 *amounts and costs for the process for*
15 *the review of in vitro clinical test sub-*
16 *missions and applications, including*
17 *identifying drivers of such changes;*
18 *and*

19 *(III) for each of the Center for De-*
20 *vices and Radiological Health, the*
21 *Center for Biologics Evaluation and*
22 *Research, the Office of Regulatory Af-*
23 *airs, and the Office of the Commis-*
24 *sioner, the number of employees for*
25 *whom time reporting is required and*

1 *the number of employees for whom*
2 *time reporting is not required.*

3 *(v) ANALYSIS.—For each fiscal year,*
4 *the Secretary shall include in the report*
5 *under clause (i) an analysis of the fol-*
6 *lowing:*

7 *(I) The difference between the ag-*
8 *gregate number of premarket applica-*
9 *tions filed under section 587B or sec-*
10 *tion 587D of the Federal Food, Drug,*
11 *and Cosmetic Act and the aggregate*
12 *number of major deficiency letters, not*
13 *approvable letters, and denials for such*
14 *applications issued by the agency, ac-*
15 *counting for—*

16 *(aa) the number of applica-*
17 *tions filed under each of sections*
18 *587B and 587D of the Federal*
19 *Food, Drug, and Cosmetic Act*
20 *during one fiscal year for which a*
21 *decision is not scheduled to be*
22 *made until the following fiscal*
23 *year; and*

24 *(bb) the aggregate number of*
25 *applications under each of sec-*

1 *tions 587B and 587D of the Fed-*
2 *eral Food, Drug, and Cosmetic*
3 *Act for each fiscal year that did*
4 *not meet the goals as identified by*
5 *the recommendations transmitted*
6 *to Congress by the Secretary pur-*
7 *suant to subsection (b)(1)(E).*

8 *(II) Relevant data to determine*
9 *whether the Center for Devices and Ra-*
10 *diological Health has met performance*
11 *enhancement goals identified by the*
12 *recommendations transmitted to Con-*
13 *gress by the Secretary pursuant to sub-*
14 *section (b)(1)(E).*

15 *(III) The most common causes*
16 *and trends for external or other cir-*
17 *cumstances affecting the ability of the*
18 *Food and Drug Administration to*
19 *meet review time and performance en-*
20 *hancement goals identified by the rec-*
21 *ommendations transmitted to Congress*
22 *by the Secretary pursuant to sub-*
23 *section (b)(1)(E).*

24 *(B) PUBLICATION.—With regard to infor-*
25 *mation to be reported by the Food and Drug Ad-*

1 *ministration to industry on a quarterly and an-*
 2 *nual basis pursuant to recommendations trans-*
 3 *mitted to Congress by the Secretary pursuant to*
 4 *subsection (b)(1)(E), the Secretary shall make*
 5 *such information publicly available on the*
 6 *website of the Food and Drug Administration*
 7 *not later than 60 days after the end of each*
 8 *quarter or 120 days after the end of each fiscal*
 9 *year, respectively, to which such information ap-*
 10 *plies.*

11 *(C) UPDATES.—The Secretary shall include*
 12 *in each report under subparagraph (A) informa-*
 13 *tion on all previous cohorts for which the Sec-*
 14 *retary has not given a complete response on all*
 15 *in vitro clinical test premarket applications and*
 16 *technology certification orders and supplements,*
 17 *premarket, and technology certification notifica-*
 18 *tions in the cohort.*

19 *(2) CORRECTIVE ACTION REPORT.—Beginning*
 20 *with fiscal year 2022, for each fiscal year for which*
 21 *fees are collected under this section, the Secretary*
 22 *shall prepare and submit a corrective action report to*
 23 *the Committee on Health, Education, Labor, and*
 24 *Pensions and the Committee on Appropriations of the*
 25 *Senate and the Committee on Energy and Commerce*

1 *and the Committee on Appropriations of the House of*
2 *Representatives. The report shall include the following*
3 *information, as applicable:*

4 (A) *GOALS MET.—For each fiscal year, if*
5 *the Secretary determines, based on the analysis*
6 *under paragraph (1)(A)(v), that each of the goals*
7 *identified by the recommendations transmitted to*
8 *Congress by the Secretary pursuant to subsection*
9 *(b)(1)(E) for the applicable fiscal year have been*
10 *met, the corrective action report shall include*
11 *recommendations on ways in which the Sec-*
12 *retary can improve and streamline the in vitro*
13 *clinical test premarket application and tech-*
14 *nology certification review process.*

15 (B) *GOALS MISSED.—For each of the goals*
16 *identified by the letters described in rec-*
17 *ommendations transmitted to Congress by the*
18 *Secretary pursuant to subsection (b)(1)(E) for*
19 *the applicable fiscal year that the Secretary de-*
20 *termines to not have been met, the corrective ac-*
21 *tion report shall include—*

22 (i) *a justification for such determina-*
23 *tion;*

24 (ii) *a description of the types of cir-*
25 *cumstances, in the aggregate, under which*

1 *applications or reports submitted under sec-*
 2 *tions 587B and 587D of the Federal Food,*
 3 *Drug, and Cosmetic Act missed the review*
 4 *goal times but were approved during the*
 5 *first cycle review, as applicable;*

6 *(iii) a summary and any trends with*
 7 *regard to the circumstances for which a re-*
 8 *view goal was missed; and*

9 *(iv) the performance enhancement*
 10 *goals that were not achieved during the pre-*
 11 *vious fiscal year and a description of efforts*
 12 *the Food and Drug Administration has put*
 13 *in place for the fiscal year in which the re-*
 14 *port is submitted to improve the ability of*
 15 *such agency to meet each such goal for the*
 16 *such fiscal year.*

17 *(3) FISCAL REPORT.—*

18 *(A) IN GENERAL.—For fiscal years 2028*
 19 *and annually thereafter, not later than 120 days*
 20 *after the end of each fiscal year during which*
 21 *fees are collected under this section, the Secretary*
 22 *shall prepare and submit to the Committee on*
 23 *Health, Education, Labor, and Pensions of the*
 24 *Senate and the Committee on Energy and Com-*
 25 *merce of the House of Representatives, a report*

1 *on the implementation of the authority for such*
 2 *fees during such fiscal year and the use, by the*
 3 *Food and Drug Administration, of the fees col-*
 4 *lected during such fiscal year for which the re-*
 5 *port is made.*

6 (B) *CONTENTS.*—*Such report shall include*
 7 *expenditures delineated by budget authority and*
 8 *user fee dollars related to administrative ex-*
 9 *penses and information technology infrastructure*
 10 *contracts and expenditures.*

11 (C) *OPERATING RESERVE.*—*Such report*
 12 *shall provide the amount of operating reserves of*
 13 *carryover user fees available each year, and any*
 14 *planned allocations or obligations of such bal-*
 15 *ance of operating reserves for the program.*

16 (4) *PUBLIC AVAILABILITY.*—*The Secretary shall*
 17 *make the reports required under paragraphs (1)*
 18 *through (3) available to the public on the website of*
 19 *the Food and Drug Administration.*

20 (5) *ENHANCED COMMUNICATION.*—

21 (A) *COMMUNICATIONS WITH CONGRESS.*—
 22 *Each fiscal year, as applicable and requested,*
 23 *representatives from the Centers with expertise*
 24 *in the review of in vitro clinical tests shall meet*
 25 *with representatives from the Committee on*

1 *Health, Education, Labor, and Pensions of the*
 2 *Senate and the Committee on Energy and Com-*
 3 *merce of the House of Representatives to report*
 4 *on the contents described in the reports under*
 5 *this section.*

6 (B) *PARTICIPATION IN CONGRESSIONAL*
 7 *HEARING.—Each fiscal year, as applicable and*
 8 *requested, representatives from the Food and*
 9 *Drug Administration shall participate in a pub-*
 10 *lic hearing before the Committee on Health, Edu-*
 11 *cation, Labor, and Pensions of the Senate and*
 12 *the Committee on Energy and Commerce of the*
 13 *House of Representatives, to report on the con-*
 14 *tents described in the reports under this section.*
 15 *Such hearing shall occur not later than 120 days*
 16 *after the end of each fiscal year for which fees*
 17 *are collected under this section.*

18 **SEC. 830. AUTHORIZATION OF APPROPRIATIONS.**

19 *For purposes of funding implementation of this sub-*
 20 *title (including the amendments made by this subtitle), in-*
 21 *cluding undertaking activities for the development of regu-*
 22 *lations and guidances, hiring of necessary staff, and the de-*
 23 *velopment of technology systems to implement this subtitle*
 24 *(including the amendments made by this subtitle) in a*
 25 *timely, effective, and efficient manner, there is authorized*

1 to be appropriated \$480,000,000, to remain available
2 through the end of fiscal year 2028.

3 **SEC. 831. GUIDANCE ON DIAGNOSTIC INNOVATION.**

4 Not later than January 1, 2025, the Secretary shall
5 issue guidance to assist developers of in vitro clinical tests
6 intended to identify or diagnose rare diseases and in vitro
7 clinical tests intended to address an unmet medical need.
8 Such guidance shall include considerations for addressing
9 barriers to developing sufficient data to demonstrate clin-
10 ical validity for such tests, such as challenges associated
11 with data collection and obstacles to the timely generation
12 of evidence.

13 **SEC. 832. GAO REPORT ON UNIQUE CONSIDERATIONS.**

14 Not later than 3 years after the date of enactment of
15 this Act, the Comptroller General of the United States shall
16 submit to the Committee on Health, Education, Labor, and
17 Pensions of the Senate and the Committee on Energy and
18 Commerce of the House of Representatives a report—

19 (1) evaluating the unique considerations for hos-
20 pital-based laboratories, laboratories serving academic
21 medical centers, and other health care practitioners,
22 as appropriate, in implementing this subtitle, includ-
23 ing the amendments made by this subtitle; and

24 (2) including recommendations based on the
25 findings of the report.

1 ***TITLE IX—OTHER PROVISIONS***

2 ***SEC. 901. FACILITIES MANAGEMENT.***

3 *(a) PDUFA AUTHORITY.—Section 736(g)(2) of the*
 4 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 5 *379h(g)(2)) is amended—*

6 *(1) in subparagraph (A)(ii)—*

7 *(A) by striking “shall be available to de-*
 8 *fray” and inserting the following: “shall be*
 9 *available—*

10 *“(I) for fiscal year 2023, to de-*
 11 *fray”;*

12 *(B) by striking the period and inserting “;*
 13 *and”; and*

14 *(C) by adding at the end the following:*

15 *“(II) for fiscal year 2024 and*
 16 *each subsequent fiscal year, to defray*
 17 *the costs of the resources allocated for*
 18 *the process for the review of human*
 19 *drug applications (including such costs*
 20 *for an additional number of full-time*
 21 *equivalent positions in the Department*
 22 *of Health and Human Services to be*
 23 *engaged in such process), only if the*
 24 *sum of the amounts allocated by the*
 25 *Secretary for such costs, excluding costs*

1 *paid from fees collected under this sec-*
 2 *tion, plus other costs for the mainte-*
 3 *nance, renovation, and repair of facili-*
 4 *ties and acquisition, maintenance, and*
 5 *repair of fixtures, furniture, and other*
 6 *necessary materials and supplies in*
 7 *connection with the process for the re-*
 8 *view of human drug applications, is no*
 9 *less than the amount allocated for such*
 10 *costs, excluding any such costs paid*
 11 *from fees collected under this section,*
 12 *for fiscal year 1997, multiplied by the*
 13 *adjustment factor.”; and*

14 (2) in subparagraph (B), by striking “for the
 15 process for the review of human drug applications”
 16 and inserting “as described in subclause (I) or (II) of
 17 such subparagraph, as applicable”.

18 (b) *BSUFA AUTHORITY*.—Section 744H(f)(2) of the
 19 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 20 *52(f)(2)) is amended—*

21 (1) in subparagraph (B)(i)—

22 (A) by striking “available for a fiscal year
 23 beginning after fiscal year 2012” and inserting
 24 the following: “available—

25 “(I) for fiscal year 2023”;

1 (B) by striking “the fiscal year involved.”
2 and inserting “such fiscal year; and”; and

3 (C) by adding at the end the following:

4 “(II) for fiscal year 2024 and
5 each subsequent fiscal year, to defray
6 the costs of the process for the review of
7 biosimilar biological product applica-
8 tions (including such costs for an addi-
9 tional number of full-time equivalent
10 positions in the Department of Health
11 and Human Services to be engaged in
12 such process), only if the sum of the
13 amounts allocated by the Secretary for
14 such costs, excluding costs paid from
15 fees collected under this section, plus
16 other costs for the maintenance, ren-
17 ovation, and repair of facilities and
18 acquisition, maintenance, and repair
19 of fixtures, furniture, and other nec-
20 essary materials and supplies in con-
21 nection with the process for the review
22 of biosimilar biological product appli-
23 cations, is no less than \$20,000,000,
24 multiplied by the adjustment factor

1 *applicable to the fiscal year involved.”;*

2 *and*

3 *(2) in subparagraph (C), by striking “subpara-*
 4 *graph (B) in any fiscal year if the costs described in*
 5 *such subparagraph” and inserting “subparagraph*
 6 *(B)(i) in any fiscal year if the costs allocated as de-*
 7 *scribed in subclause (I) or (II) of such subparagraph,*
 8 *as applicable,”.*

9 *(c) GDUFA AUTHORITY.—Section 744B of the Federal*
 10 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42) is*
 11 *amended—*

12 *(1) in subsection (e)(2), by striking*
 13 *“744A(11)(C)” and inserting “744A(12)(C)”;* *and*

14 *(2) in subsection (i)(2)—*

15 *(A) in subparagraph (A)(ii)—*

16 *(i) by striking “available for a fiscal*
 17 *year beginning after fiscal year 2012” and*
 18 *inserting the following: “available—*

19 *“(I) for fiscal year 2023”;*

20 *(ii) by striking “the fiscal year in-*
 21 *volved.” and inserting “such fiscal year;*
 22 *and”;* *and*

23 *(iii) by adding at the end the fol-*
 24 *lowing:*

1 “(II) for fiscal year 2024 and
2 each subsequent fiscal year, to defray
3 the costs of human generic drug activi-
4 ties (including such costs for an addi-
5 tional number of full-time equivalent
6 positions in the Department of Health
7 and Human Services to be engaged in
8 such activities), only if the sum of the
9 amounts allocated by the Secretary for
10 such costs, excluding costs paid from
11 fees collected under this section, plus
12 other costs for the maintenance, ren-
13 ovation, and repair of facilities and
14 acquisition, maintenance, and repair
15 of fixtures, furniture, and other nec-
16 essary materials and supplies in con-
17 nection with human generic drug ac-
18 tivities, is no less than \$97,000,000
19 multiplied by the adjustment factor de-
20 fined in section 744A(3) applicable to
21 the fiscal year involved.”; and

22 (B) in subparagraph (B), by striking “for
23 human generic activities” and inserting “as de-
24 scribed in subclause (I) or (II) of such subpara-
25 graph, as applicable.”.

1 (d) *MDUFA AUTHORITY*.—Section 738 of the Federal
 2 *Food, Drug, and Cosmetic Act* (21 U.S.C. 379j) is amend-
 3 ed—

4 (1) in subsection (h)(2)—

5 (A) in subparagraph (A)(ii)—

6 (i) by striking “shall be available to
 7 defray” and inserting the following: “shall
 8 be available—

9 “(I) for fiscal year 2023, to de-
 10 fray”;

11 (ii) by striking the period and insert-
 12 ing “; and”; and

13 (iii) by adding at the end the fol-
 14 lowing:

15 “(II) for fiscal year 2024 and
 16 each subsequent fiscal year, to defray
 17 the costs of the resources allocated for
 18 the process for the review of device ap-
 19 plications (including such costs for an
 20 additional number of full-time equiva-
 21 lent positions in the Department of
 22 Health and Human Services to be en-
 23 gaged in such process), only if the sum
 24 of the amounts allocated by the Sec-
 25 retary for such costs, excluding costs

1 *paid from fees collected under this sec-*
 2 *tion, plus other costs for the mainte-*
 3 *nance, renovation, and repair of facili-*
 4 *ties and acquisition, maintenance, and*
 5 *repair of fixtures, furniture and other*
 6 *necessary materials and supplies in*
 7 *connection with the process for the re-*
 8 *view of device applications, is no less*
 9 *than the amount allocated for such*
 10 *costs, excluding any such costs paid*
 11 *from fees collected under this section,*
 12 *for fiscal year 2009 multiplied by the*
 13 *adjustment factor.”; and*

14 *(B) in subparagraph (B)(i), in the matter*
 15 *preceding subclause (I), by striking “for the*
 16 *process for the review of device applications” and*
 17 *inserting “as described in subclause (I) or (II) of*
 18 *such subparagraph, as applicable”; and*

19 *(2) in subsection (g)(3), by striking “737(9)(C)”*
 20 *and inserting “737(10)(C)”.*

21 *(e) TECHNICAL CORRECTION.—*

22 *(1) IN GENERAL.—Section 905(b)(2) of the FDA*
 23 *Reauthorization Act of 2017 (Public Law 115–52) is*
 24 *amended by striking “Section 738(h) of the Federal*
 25 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)) is*

1 *amended” and inserting “Subsection (g) of section*
 2 *738 of the Federal Food, Drug, and Cosmetic Act (21*
 3 *U.S.C. 379j), as so redesignated by section*
 4 *203(f)(2)(B)(i), is amended”.*

5 (2) *EFFECTIVE DATE.*—*The amendment made by*
 6 *paragraph (1) shall take effect as though included in*
 7 *the enactment of section 905 of the FDA Reauthoriza-*
 8 *tion Act of 2017 (Public Law 115–52).*

9 **SEC. 902. USER FEE PROGRAM TRANSPARENCY AND AC-**
 10 **COUNTABILITY.**

11 (a) *PDUFA.*—

12 (1) *REAUTHORIZATION; REPORTING REQUIRE-*
 13 *MENTS.*—*Section 736B(a) of the Federal Food, Drug,*
 14 *and Cosmetic Act (21 U.S.C. 379h–2(a)) is amend-*
 15 *ed—*

16 (A) *in paragraph (1)—*

17 (i) *in subparagraph (B)—*

18 (I) *in clause (vii), by striking “;*
 19 *and” and inserting a semicolon;*

20 (II) *in clause (viii), by striking*
 21 *the period and inserting “; and”; and*

22 (III) *by adding at the end the fol-*
 23 *lowing:*

24 “(ix) *the number of investigational*
 25 *new drug applications submitted per fiscal*

1 year, including for each review division.”;

2 and

3 (ii) by adding at the end the following

4 flush text:

5 “Nothing in subparagraph (B) shall be construed to
6 authorize the disclosure of information that is prohib-
7 ited from disclosure under section 301(j) of this Act
8 or section 1905 of title 18, United States Code, or
9 that is subject to withholding under section 552(b)(4)
10 of title 5, United States Code.”; and

11 (B) in paragraph (4)—

12 (i) by amending subparagraph (A) to
13 read as follows:

14 “(A) data, analysis, and discussion of the
15 changes in the number of individuals hired as
16 agreed upon in the letters described in section
17 101(b) of the Prescription Drug User Fee
18 Amendments of 2022 and the number of remain-
19 ing vacancies, the number of full-time equiva-
20 lents funded by fees collected pursuant to section
21 736, and the number of full-time equivalents
22 funded by budget authority at the Food and
23 Drug Administration by each division within the
24 Center for Drug Evaluation and Research, the
25 Center for Biologics Evaluation and Research,

1 *the Office of Regulatory Affairs, and the Office*
 2 *of the Commissioner;”;*

3 *(ii) by amending subparagraph (B) to*
 4 *read as follows:*

5 *“(B) data, analysis, and discussion of the*
 6 *changes in the fee revenue amounts and costs for*
 7 *the process for the review of human drug appli-*
 8 *cations, including identifying—*

9 *“(i) drivers of such changes; and*

10 *“(ii) changes in the average total cost*
 11 *per full-time equivalent in the prescription*
 12 *drug review program;”;*

13 *(iii) in subparagraph (C), by striking*
 14 *the period and inserting “; and”; and*

15 *(iv) by adding at the end the following:*

16 *“(D) data, analysis, and discussion of the*
 17 *changes in the average full-time equivalent hours*
 18 *required to complete review of each type of*
 19 *human drug application.”.*

20 (2) *REAUTHORIZATION.*—*Section 736B(f) of the*
 21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 22 *379h–2(f)) is amended—*

23 *(A) by redesignating paragraphs (4)*
 24 *through (6) as paragraphs (5) through (7), re-*
 25 *spectively;*

1 (B) by inserting after paragraph (3) the fol-
 2 lowing:

3 “(4) *UPDATES TO CONGRESS.*—*The Secretary, in*
 4 *consultation with regulated industry, shall provide*
 5 *regular updates on negotiations on the reauthoriza-*
 6 *tion of this part to the Committee on Health, Edu-*
 7 *cation, Labor, and Pensions of the Senate and the*
 8 *Committee on Energy and Commerce of the House of*
 9 *Representatives.*”; and

10 (C) in paragraph (7), as so redesignated—

11 (i) in subparagraph (A)—

12 (I) by striking “Before presenting
 13 the recommendations developed under
 14 paragraphs (1) through (5) to the Con-
 15 gress, the” and inserting “The”; and

16 (II) by inserting “, not later than
 17 30 days after each such negotiation
 18 meeting” before the period at the end;
 19 and

20 (ii) in subparagraph (B), by inserting
 21 “, in sufficient detail,” after “shall summa-
 22 rize”.

23 (b) *MDUFA.*—

24 (1) *REAUTHORIZATION; REPORTING REQUIRE-*
 25 *MENTS.*—*Section 738A(a)(1)(A) of the Federal Food,*

1 *Drug, and Cosmetic Act (21 U.S.C. 379j-1(a)(1)(A)),*
2 *as amended by section 204, is further amended—*

3 *(A) in clause (ii)—*

4 *(i) in subclause (II), by striking “;*
5 *and” and inserting a semicolon;*

6 *(ii) in subclause (III), by striking the*
7 *period and inserting a semicolon; and*

8 *(iii) by adding at the end the fol-*
9 *lowing:*

10 *“(IV) the number of investiga-*
11 *tional device exemption applications*
12 *submitted under section 520(g) per fis-*
13 *cal year, including for each review di-*
14 *vision; and*

15 *“(V) the number of expedited de-*
16 *velopment and priority review requests*
17 *and designations under section 515B*
18 *per fiscal year, including for each re-*
19 *view division.*

20 *Nothing in this clause shall be construed to*
21 *authorize the disclosure of information that*
22 *is prohibited from disclosure under section*
23 *301(j) of this Act or section 1905 of title 18,*
24 *United States Code, or that is subject to*

1 *withholding under section 552(b)(4) of title*
2 *5, United States Code.”; and*

3 *(B) in clause (iv) (relating to rationale for*
4 *MDUFA program changes)—*

5 *(i) by amending subclause (I) to read*
6 *as follows:*

7 *“(I) data, analysis, and discus-*
8 *sion of the changes in the number of*
9 *individuals hired as agreed upon in*
10 *the letters described in section 201(b) of*
11 *the Medical Device User Fee Amend-*
12 *ments of 2022 and the number of re-*
13 *maining vacancies, the number of full-*
14 *time equivalents funded by fees col-*
15 *lected pursuant to section 738, and the*
16 *number of full time equivalents funded*
17 *by budget authority at the Food and*
18 *Drug Administration by each division*
19 *within the Center for Devices and Ra-*
20 *diological Health, the Center for Bio-*
21 *logics Evaluation and Research, the*
22 *Office of Regulatory Affairs, and the*
23 *Office of the Commissioner;”;*

24 *(ii) by amending subclause (II) to read*
25 *as follows:*

1 “(II) data, analysis, and discus-
 2 sion of the changes in the fee revenue
 3 amounts and costs for the process for
 4 the review of device applications, in-
 5 cluding identifying—

6 “(aa) drivers of such changes;
 7 and

8 “(bb) changes in the average
 9 total cost per full-time equivalent
 10 in the medical device review pro-
 11 gram;”;

12 (iii) in subclause (III), by striking the
 13 period and inserting “; and”; and

14 (iv) by adding at the end the following:

15 “(IV) data, analysis, and discus-
 16 sion of the changes in the average full-
 17 time equivalent hours required to com-
 18 plete review of medical device applica-
 19 tion types.”.

20 (2) *REAUTHORIZATION*.—Section 738A(b) of the
 21 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
 22 379j–1(b)), as amended by section 204, is further
 23 amended—

1 (A) by redesignating paragraphs (4)
2 through (6) as paragraphs (5) through (7), re-
3 spectively;

4 (B) by inserting after paragraph (3) the fol-
5 lowing:

6 “(4) *UPDATES TO CONGRESS.*—*The Secretary, in*
7 *consultation with regulated industry, shall provide*
8 *regular updates on negotiations on the reauthoriza-*
9 *tion of this part to the Committee on Health, Edu-*
10 *cation, Labor, and Pensions of the Senate and the*
11 *Committee on Energy and Commerce of the House of*
12 *Representatives.*”; and

13 (C) in paragraph (7), as so redesignated—

14 (i) in subparagraph (A)—

15 (I) by striking “Before presenting
16 the recommendations developed under
17 paragraphs (1) through (5) to the Con-
18 gress, the” and inserting “The”; and

19 (II) by inserting “, not later than
20 30 days after each such negotiation
21 meeting” before the period at the end;
22 and

23 (ii) in subparagraph (B), by inserting
24 “, in sufficient detail,” after “shall summa-
25 rize”.

1 (c) *GDUFA*.—

2 (1) *REAUTHORIZATION; REPORTING REQUIRE-*
3 *MENTS*.—Section 744C(a)(3) of the *Federal Food,*
4 *Drug, and Cosmetic Act* (21 U.S.C. 379j–43(a)(3)) is
5 amended—

6 (A) in the matter preceding subparagraph
7 (A), by striking “fiscal year 2020” and inserting
8 “fiscal year 2023”;

9 (B) by amending subparagraph (A) to read
10 as follows:

11 “(A) data, analysis, and discussion of the
12 changes in the number of individuals hired as
13 agreed upon in the letters described in section
14 301(b) of the *Generic Drug User Fee Amend-*
15 *ments of 2022* and the number of remaining va-
16 cancies, the number of full-time equivalents fund-
17 ed by fees collected pursuant to section 744B,
18 and the number of full time equivalents funded
19 by budget authority at the Food and Drug Ad-
20 ministration by each division within the Center
21 for Drug Evaluation and Research, the Center
22 for Biologics Evaluation and Research, the Office
23 of Regulatory Affairs, and the Office of the Com-
24 missioner;”;

1 (C) by amending subparagraph (B) to read
2 as follows:

3 “(B) data, analysis, and discussion of the
4 changes in the fee revenue amounts and costs for
5 human generic drug activities, including—

6 “(i) identifying drivers of such
7 changes; and

8 “(ii) changes in the total average cost
9 per full-time equivalent in the generic drug
10 review program;”;

11 (D) in subparagraph (C), by striking the
12 period at the end and inserting “; and”; and

13 (E) by adding at the end the following:

14 “(D) data, analysis, and discussion of the
15 changes in the average full-time equivalent hours
16 required to complete review of each type of abbrevi-
17 ated new drug application.”.

18 (2) *REAUTHORIZATION*.—Section 744C(f) of the
19 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
20 379j–43(f)) is amended—

21 (A) by redesignating paragraphs (4)
22 through (6) as paragraphs (5) through (7), re-
23 spectively;

24 (B) by inserting after paragraph (3) the fol-
25 lowing:

1 “(4) *UPDATES TO CONGRESS.*—*The Secretary, in*
 2 *consultation with regulated industry, shall provide*
 3 *regular updates on negotiations on the reauthoriza-*
 4 *tion of this part to the Committee on Health, Edu-*
 5 *cation, Labor, and Pensions of the Senate and the*
 6 *Committee on Energy and Commerce of the House of*
 7 *Representatives.*”; and

8 (C) *in paragraph (7), as so redesignated—*

9 (i) *in subparagraph (A)—*

10 (I) *by striking “Before presenting*
 11 *the recommendations developed under*
 12 *paragraphs (1) through (5) to the Con-*
 13 *gress, the” and inserting “The”; and*

14 (II) *by inserting “, not later than*
 15 *30 days after each such negotiation*
 16 *meeting” before the period at the end;*
 17 *and*

18 (ii) *in subparagraph (B), by inserting*
 19 *“, in sufficient detail,” after “shall summa-*
 20 *rize”.*

21 (d) *BSUFA.—*

22 (1) *REAUTHORIZATION; REPORTING REQUIRE-*
 23 *MENTS.*—*Section 744I(a)(4) of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)(4)) is*
 25 *amended—*

1 (A) by amending subparagraph (A) to read
2 as follows:

3 “(A) data, analysis, and discussion of the
4 changes in the number of individuals hired as
5 agreed upon in the letters described in section
6 401(b) of the Biosimilar User Fee Amendments
7 of 2022 and the number of remaining vacancies,
8 the number of full-time equivalents funded by
9 fees collected pursuant to section 744H, and the
10 number of full time equivalents funded by budget
11 authority at the Food and Drug Administration
12 by each division within the Center for Drug
13 Evaluation and Research, the Center for Bio-
14 logics Evaluation and Research, the Office of
15 Regulatory Affairs, and the Office of the Com-
16 missioner;”;

17 (B) by amending subparagraph (B) to read
18 as follows:

19 “(B) data, analysis, and discussion of the
20 changes in the fee revenue amounts and costs for
21 the process for the review of biosimilar biological
22 product applications, including identifying—

23 “(i) drivers of such changes; and

1 “(ii) changes in the average total cost
2 per full-time equivalent in the biosimilar
3 biological product review program;”;

4 (C) in subparagraph (C), by striking the
5 period at the end and inserting “; and”; and

6 (D) by adding at the end the following:

7 “(D) data, analysis, and discussion of the
8 changes in the average full-time equivalent hours
9 required to complete review of each type of bio-
10 similar biological product application.”.

11 (2) *REAUTHORIZATION*.—Section 744I(f) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379j–53(f)) is amended—

14 (A) by redesignating paragraphs (2) and
15 (3) as paragraphs (5) and (6), respectively;

16 (B) by inserting after paragraph (1) the fol-
17 lowing:

18 “(2) *PRIOR PUBLIC INPUT*.—Prior to beginning
19 negotiations with the regulated industry on the reau-
20 thorization of this part, the Secretary shall—

21 “(A) publish a notice in the Federal Reg-
22 ister requesting public input on the reauthoriza-
23 tion;

1 “(B) hold a public meeting at which the
2 public may present its views on the reauthoriza-
3 tion;

4 “(C) provide a period of 30 days after the
5 public meeting to obtain written comments from
6 the public suggesting changes to this part; and

7 “(D) publish the comments on the Food and
8 Drug Administration’s website.

9 “(3) *PERIODIC CONSULTATION.*—Not less fre-
10 quently than once every month during negotiations
11 with the regulated industry, the Secretary shall hold
12 discussions with representatives of patient and con-
13 sumer advocacy groups to continue discussions of
14 their views on the reauthorization and their sugges-
15 tions for changes to this part as expressed under
16 paragraph (2).

17 “(4) *UPDATES TO CONGRESS.*—The Secretary, in
18 consultation with regulated industry, shall provide
19 regular updates on negotiations on the reauthoriza-
20 tion of this part to the Committee on Health, Edu-
21 cation, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House of
23 Representatives.”; and

24 (C) by adding at the end the following:

25 “(7) *MINUTES OF NEGOTIATION MEETINGS.*—

1 “(A) *PUBLIC AVAILABILITY.*—*The Secretary*
2 *shall make publicly available, on the public*
3 *website of the Food and Drug Administration,*
4 *minutes of all negotiation meetings conducted*
5 *under this subsection between the Food and Drug*
6 *Administration and the regulated industry, not*
7 *later than 30 days after each such negotiation*
8 *meeting.*

9 “(B) *CONTENT.*—*The minutes described*
10 *under subparagraph (A) shall summarize, in suf-*
11 *ficient detail, any substantive proposal made by*
12 *any party to the negotiations as well as signifi-*
13 *cant controversies or differences of opinion dur-*
14 *ing the negotiations and their resolution.”.*

15 **SEC. 903. OTC HEARING AIDS FINAL RULE.**

16 *Not later than 30 days after the date of enactment of*
17 *this Act, the Secretary of Health and Human Services shall*
18 *issue a final rule to establish a category of over-the-counter*
19 *hearing aids, as defined in subsection (q) of section 520 of*
20 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j),*
21 *as described in section 709(b) of the FDA Reauthorization*
22 *Act of 2017 (Public Law 115–52).*

1 **SEC. 904. ENHANCING COORDINATION AND TRANSPARENCY**
 2 **ON INSPECTIONS.**

3 (a) *COORDINATION.*—Section 506D of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is amend-
 5 ed—

6 (1) *by adding at the end the following:*

7 “(g) *COORDINATION.*—The Secretary shall ensure
 8 timely and effective internal coordination and alignment
 9 among the field investigators of the Food and Drug Admin-
 10 istration and the staff of the Center for Drug Evaluation
 11 and Research’s Office of Compliance and Drug Shortage
 12 Program regarding the reviews of reports shared pursuant
 13 to section 704(b)(2), and any feedback or corrective or pre-
 14 ventive actions in response to such reports.”; and

15 (2) *by amending subsection (f) to read as follows:*

16 “(f) *TEMPORARY SUNSET.*—Subsection (a) shall cease
 17 to be effective on the date that is 5 years after the date of
 18 enactment of the Food and Drug Administration Safety
 19 and Innovation Act. Subsections (b), (c), and (e) shall not
 20 be in effect during the period beginning 5 years after the
 21 date of enactment of the Food and Drug Administration
 22 Safety and Innovation Act and ending on the date of enact-
 23 ment of the Food and Drug Administration Safety and
 24 Landmark Advancements Act of 2022. Subsections (b), (c),
 25 and (e) shall be in effect beginning on the date of enactment

1 *of the Food and Drug Administration Safety and Land-*
 2 *mark Advancements Act of 2022.”.*

3 (b) *REPORTING.*—Section 506C–1(a) of the Federal
 4 *Food, Drug, and Cosmetic Act* (21 U.S.C. 356c–1(a)) is
 5 *amended—*

6 (1) *by redesignating paragraphs (3) through (7)*
 7 *as paragraphs (4) through (8), respectively;*

8 (2) *by inserting after paragraph (2) the fol-*
 9 *lowing:*

10 “(3) *provides the number of reports that were re-*
 11 *quired under section 704(b)(2) to be sent to the ap-*
 12 *propriate offices of the Food and Drug Administra-*
 13 *tion with expertise regarding drug shortages, and the*
 14 *number of such reports that were sent;”;* and

15 (3) *in paragraph (4)(A), as so redesignated, by*
 16 *striking “paragraph (7)” and inserting “paragraph*
 17 *(8)”.*

18 (c) *APPLICABILITY.*—

19 (1) *SUBSECTION (a).*—*The amendments made by*
 20 *subsection (a) shall apply beginning on the date of*
 21 *enactment of this Act.*

22 (2) *SUBSECTION (b).*—*The amendments made by*
 23 *subsection (b) shall apply beginning on the date that*
 24 *is 1 year after the date of enactment of this Act.*

1 (d) *REPORTING OF MUTUAL RECOGNITION AGREE-*
 2 *MENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.*—*Sec-*
 3 *tion 510(h) of the Federal Food, Drug, and Cosmetic Act*
 4 *(21 U.S.C. 360(h)) is amended—*

5 (1) *in paragraph (6)—*

6 (A) *in subparagraph (A), by striking*
 7 *clauses (i) and (ii) and inserting the following:*

8 “(i) *the number of domestic and foreign es-*
 9 *tablishments registered pursuant to this section*
 10 *in the previous fiscal year;*

11 “(ii) *the number of such registered establish-*
 12 *ments in each region of interest;*

13 “(iii) *the number of such domestic establish-*
 14 *ments and the number of such foreign establish-*
 15 *ments, including the number of establishments in*
 16 *each region of interest, that the Secretary in-*
 17 *spected in the previous fiscal year;*

18 “(iv) *the number of inspections to support*
 19 *actions by the Secretary on applications under*
 20 *section 505 of this Act or section 351 of the Pub-*
 21 *lic Health Service Act, including the number of*
 22 *inspections to support actions by the Secretary*
 23 *on supplemental applications, including changes*
 24 *to manufacturing processes, the Secretary con-*
 25 *ducted in the previous fiscal year;*

1 “(v) the number of routine surveillance in-
 2 spections the Secretary conducted in the previous
 3 fiscal year, including in each region of interest;

4 “(vi) the number of for-cause inspections the
 5 Secretary conducted in the previous fiscal year,
 6 not including inspections described in clause
 7 (iv), including in each region of interest; and

8 “(vii) the number of inspections the Sec-
 9 retary has recognized pursuant to an agreement
 10 entered into pursuant to section 809, or other-
 11 wise recognized, for each of the types of inspec-
 12 tions described in clauses (v) and (vi), including
 13 for inspections of establishments in each region
 14 of interest.”;

15 (B) in subparagraph (B), by striking “;
 16 and” and inserting a semicolon;

17 (C) in subparagraph (C), by striking the
 18 period and inserting “; and”; and

19 (D) by adding at the end the following:

20 “(D) the status of the efforts of the Food
 21 and Drug Administration to expand its recogni-
 22 tion of inspections conducted or recognized by
 23 foreign regulatory authorities under section 809,
 24 including any obstacles to expanding the use of
 25 such recognition.”; and

1 (2) *by adding at the end the following:*

2 “(7) *REGION OF INTEREST.*—For purposes of
3 *paragraph (6)(A), the term ‘region of interest’ means*
4 *a foreign geographic region or country, including the*
5 *People’s Republic of China, India, the European*
6 *Union, the United Kingdom, and any other country*
7 *or geographic region, as the Secretary determines ap-*
8 *propriate.”.*

9 (e) *ENHANCING TRANSPARENCY OF DRUG FACILITY*
10 *INSPECTION TIMELINES.*—Section 902 of the *FDA Reau-*
11 *thorization Act of 2017 (21 U.S.C. 355 note) is amended*
12 *to read as follows:*

13 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

14 *“Not later than 120 days after the end of each fiscal*
15 *year, the Secretary of Health and Human Services shall*
16 *post on the website of the Food and Drug Administration*
17 *information related to inspections of facilities necessary for*
18 *approval of a drug under subsection (c) or (j) of section*
19 *505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
20 *355) or approval of a device under section 515 of such Act*
21 *(21 U.S.C. 360e) that were conducted during the previous*
22 *fiscal year. Such information shall include the following:*

23 “(1) *The median time following a request from*
24 *staff of the Food and Drug Administration reviewing*

1 *an application or report to the beginning of the in-*
 2 *spection, including—*

3 *“(A) the median time for drugs described in*
 4 *505(j)(11)(A)(i) of the Federal Food, Drug, and*
 5 *Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));*

6 *“(B) the median time for drugs for which a*
 7 *notification has been submitted in accordance*
 8 *with section 506C(a) of such Act (21 U.S.C.*
 9 *356c(a)) during the previous fiscal year; and*

10 *“(C) the median time for drugs on the drug*
 11 *shortage list in effect under section 506E of such*
 12 *Act (21 U.S.C. 356e) at the time of such request.*

13 *“(2) The median time from the issuance of a re-*
 14 *port pursuant to section 704(b) of the Federal Food,*
 15 *Drug, and Cosmetic Act (21 U.S.C. 374(b)) to the*
 16 *sending of a warning letter, issuance of an import*
 17 *alert, or holding of a regulatory meeting for inspec-*
 18 *tions for which the Secretary concluded that regu-*
 19 *latory or enforcement action was indicated, including*
 20 *the median time for each category of drugs listed in*
 21 *subparagraphs (A) through (C) of paragraph (1).*

22 *“(3) The median time from the sending of a*
 23 *warning letter, issuance of an import alert, or hold-*
 24 *ing of a regulatory meeting related to conditions ob-*
 25 *served by the Secretary during an inspection, to the*

1 *time at which the Secretary concludes that corrective*
2 *actions to resolve such conditions have been taken.*

3 “(4) *The median time spent by staff of the Food*
4 *and Drug Administration at a facility during an in-*
5 *spection, including—*

6 “(A) *the median time when records were*
7 *provided remotely in accordance with a request*
8 *under section 704(a)(4) of the Federal Food,*
9 *Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)) in*
10 *advance of the inspection; and*

11 “(B) *the median time when a request for*
12 *records pursuant to such section 704(a)(4) was*
13 *not issued, or complied with, in advance of the*
14 *inspection.*

15 “(5) *The number and type of violations identi-*
16 *fied during inspections when a request for records*
17 *pursuant to such section 704(a)(4) was issued and*
18 *complied with in advance of the inspection, versus*
19 *when a request for records pursuant to such section*
20 *704(a)(4) was not issued or complied with.*

21 “(6) *The number of facilities that did not imple-*
22 *ment adequate corrective or preventive actions fol-*
23 *lowing a report issued pursuant to such section*
24 *704(b), resulting in a withhold recommendation for*
25 *an application under review, including the number of*

1 *such facilities manufacturing each category of drugs*
 2 *listed in subparagraphs (A) through (C) of paragraph*
 3 *(1).”.*

4 **SEC. 905. CERTIFICATES TO FOREIGN GOVERNMENTS.**

5 *Section 801(e)(4) of the Federal Food, Drug, and Cos-*
 6 *metic Act (21 U.S.C. 381(e)(4)) is amended—*

7 *(1) in subparagraph (E), by striking clause (iii);*
 8 *and*

9 *(2) by adding at the end the following:*

10 *“(F)(i) This paragraph applies to requests for certifi-*
 11 *cation under this subparagraph of a device manufactured*
 12 *by a device establishment located outside of the United*
 13 *States that is registered under section 510, if the device is*
 14 *listed pursuant to section 510(j), the device has been cleared,*
 15 *approved, or is not required to submit a premarket report*
 16 *pursuant to subsection (l) or (m) of section 510, and the*
 17 *device is imported or offered for import into the United*
 18 *States.*

19 *“(ii) The Secretary shall issue the certification as de-*
 20 *scribed in clause (iii) if the device or devices for which cer-*
 21 *tification is requested under this subparagraph meet the ap-*
 22 *plicable requirements of this Act.*

23 *“(iii)(I) A certification for a device described in clause*
 24 *(i) shall be subject to the fee described in subparagraph (B).*

1 “(II) Notwithstanding subparagraph (C), a certifi-
 2 cation for a device described in clause (i) shall address and
 3 include the same material information as a ‘Certificate to
 4 Foreign Government’ and shall have a document title in-
 5 cluding the words ‘Certificate to Foreign Government’.

6 “(iv) The requirements and procedures of subpara-
 7 graph (E) shall apply to a denial of a certification under
 8 this subparagraph.”.

9 **SEC. 906. IMPORTATION OF DRUGS.**

10 (a) *IN GENERAL.*—Section 804 of the Federal Food,
 11 Drug, and Cosmetic Act (21 U.S.C. 384) is amended to read
 12 as follows:

13 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

14 “(a) *DEFINITIONS.*—In this section:

15 “(1) *FOREIGN SELLER.*—The term ‘foreign seller’
 16 means an establishment within Canada engaged in
 17 the distribution of an eligible prescription drug that
 18 is imported or offered for importation into the United
 19 States, that—

20 “(A) has an active Drug Establishment Li-
 21 cense to wholesale drugs by the appropriate Ca-
 22 nadian regulatory authority;

23 “(B) is registered with the applicable regu-
 24 latory authorities to distribute drugs approved

1 *by the appropriate Canadian regulatory author-*
 2 *ity;*

3 “(C) *is not licensed by a regulatory author-*
 4 *ity with an international pharmacy license that*
 5 *allows it to distribute drugs that are approved*
 6 *by countries other than Canada and that are not*
 7 *approved by the appropriate Canadian regu-*
 8 *latory authority for distribution in Canada; and*

9 “(D) *is registered with the Secretary under*
 10 *this section.*

11 “(2) *IMPORTER.—The term ‘importer’ means a*
 12 *pharmacist or wholesaler.*

13 “(3) *PHARMACIST.—The term ‘pharmacist’*
 14 *means a person licensed by a State to practice phar-*
 15 *macy, including the dispensing and selling of pre-*
 16 *scription drugs.*

17 “(4) *PRESCRIPTION DRUG.—The term ‘prescrip-*
 18 *tion drug’ means a drug subject to section 503(b),*
 19 *other than—*

20 “(A) *a controlled substance (as defined in*
 21 *section 102 of the Controlled Substances Act (21*
 22 *U.S.C. 802));*

23 “(B) *a biological product (as defined in sec-*
 24 *tion 351 of the Public Health Service Act (42*
 25 *U.S.C. 262));*

1 “(C) *an infused drug (including a peri-*
2 *toneal dialysis solution);*

3 “(D) *an intravenously injected drug;*

4 “(E) *a drug that is inhaled during surgery;*

5 “(F) *an intrathecally or intraocularly in-*
6 *jected drug;*

7 “(G) *a drug that is subject to a risk evalua-*
8 *tion and mitigation strategy under section 505-*
9 *1;*

10 “(H) *a drug that is not a ‘product’ for pur-*
11 *poses of section 582 as defined in section*
12 *581(13);*

13 “(I) *a compounded drug; or*

14 “(J) *a drug the importation of which pur-*
15 *suant to subsection (b) is determined by the Sec-*
16 *retary to pose a threat to the public health.*

17 “(5) *QUALIFYING LABORATORY.—The term*
18 *‘qualifying laboratory’ means a laboratory in the*
19 *United States that complies with the applicable cur-*
20 *rent good manufacturing practice requirements and*
21 *has been approved by the Secretary for the purposes*
22 *of this section.*

23 “(6) *SECTION 804 IMPORTATION PROGRAM SPON-*
24 *SOR.—The term ‘section 804 importation program*
25 *sponsor’ means a State or Indian Tribe that regulates*

1 *wholesale drug distribution and the practice of phar-*
 2 *macy, or a pharmacist or wholesaler that is not the*
 3 *importer, as the Secretary may determine, that sub-*
 4 *mits a proposal to the Secretary that describes a pro-*
 5 *gram to facilitate the importation of prescription*
 6 *drugs from Canada under this section and is respon-*
 7 *sible for oversight of the implementation of the pro-*
 8 *gram.*

9 “(7) *WHOLESALER.*—*The term ‘wholesaler’—*

10 *“(A) means a person licensed (as defined in*
 11 *section 581(9)(A)) as a wholesale distributor (as*
 12 *defined in section 581(29)); and*

13 *“(B) excludes a person authorized to import*
 14 *drugs under section 801(d)(1).*

15 “(b) *REGULATIONS.*—*The Secretary, after consultation*
 16 *with the United States Trade Representative and the Com-*
 17 *missioner of Customs, shall promulgate regulations permit-*
 18 *ting time-limited section 804 importation programs, which*
 19 *shall be authorized by the Secretary and managed by States*
 20 *or Indian Tribes, or in certain circumstances by phar-*
 21 *macists and wholesalers, to import prescription drugs from*
 22 *Canada into the United States. The time limit for a section*
 23 *804 importation program authorized by the Secretary may*
 24 *be extended for a period not to exceed the initial time limit*
 25 *authorized by the Secretary.*

1 “(c) *LIMITATION.*—*The regulations under subsection*
 2 *(b) shall—*

3 “(1) *require that safeguards be in place to ensure*
 4 *that each prescription drug imported under the regu-*
 5 *lations complies with section 505 (including with re-*
 6 *spect to being safe and effective for the intended use*
 7 *of the prescription drug), with sections 501 and 502,*
 8 *and with other applicable requirements of this Act;*

9 “(2) *require that a section 804 importation pro-*
 10 *gram sponsor and an importer of a prescription drug*
 11 *under the regulations comply with subsections (d)(1),*
 12 *(d)(2), (d)(3), and (e);*

13 “(3) *require that the section 804 importation*
 14 *program sponsor demonstrates that the importation*
 15 *program meets the certification requirements under*
 16 *subsection (l)(1); and*

17 “(4) *contain any additional provisions deter-*
 18 *mined by the Secretary to be appropriate as a safe-*
 19 *guard to protect the public health or as a means to*
 20 *facilitate the importation of prescription drugs.*

21 “(d) *INFORMATION AND RECORDS.*—

22 “(1) *IN GENERAL.*—*The regulations under sub-*
 23 *section (b) shall require an importer of a prescription*
 24 *drug under subsection (b) to submit to the Secretary*
 25 *the following information and documentation:*

1 “(A) *The name and quantity of the active*
2 *ingredient of the prescription drug.*

3 “(B) *A description of the dosage form of the*
4 *prescription drug.*

5 “(C) *The date on which the prescription*
6 *drug is shipped.*

7 “(D) *The quantity of the prescription drug*
8 *that is shipped.*

9 “(E) *The point of origin and destination of*
10 *the prescription drug.*

11 “(F) *The price paid by the importer for the*
12 *prescription drug.*

13 “(G) *Documentation from the foreign seller*
14 *specifying—*

15 “(i) *the original source of the prescrip-*
16 *tion drug; and*

17 “(ii) *the quantity of each lot of the*
18 *prescription drug originally received by the*
19 *seller from that source.*

20 “(H) *The lot or control number assigned to*
21 *the prescription drug by the manufacturer of the*
22 *prescription drug.*

23 “(I) *The name, address, telephone number,*
24 *and professional license number (if any) of the*
25 *importer.*

1 “(J) Documentation demonstrating that the
2 prescription drug was received by the foreign
3 seller from the manufacturer and subsequently
4 shipped by the foreign seller to the importer.

5 “(K) Documentation of the quantity of each
6 lot of the prescription drug received by the for-
7 eign seller demonstrating that the quantity being
8 imported into the United States is not more than
9 the quantity that was received by the foreign sell-
10 er.

11 “(L)(i) In the case of an initial imported
12 shipment, documentation demonstrating that
13 each batch of the prescription drug in the ship-
14 ment was statistically sampled and tested for au-
15 thenticity and degradation.

16 “(ii) In the case of any subsequent ship-
17 ment, documentation demonstrating that a sta-
18 tistically valid sample of the shipment was tested
19 for authenticity and degradation.

20 “(M) Documentation that each supply
21 chain under a section 804 importation program
22 proposal is limited to one manufacturer, one for-
23 eign seller, and one importer.

24 “(N) For each prescription drug imported
25 under a section 804 importation program, docu-

1 *mentation that the prescription drug was pur-*
2 *chased directly from the manufacturer by the for-*
3 *ign seller and that the foreign seller sold the*
4 *prescription drug directly to the importer.*

5 *“(O) Certification from the importer that*
6 *the prescription drug—*

7 *“(i) is approved for marketing in the*
8 *United States and is not adulterated or*
9 *misbranded; and*

10 *“(ii) is relabeled after the Secretary*
11 *has accepted the results of testing required*
12 *by subparagraphs (J) through (P)) and*
13 *meets all labeling requirements under this*
14 *Act.*

15 *“(P) Laboratory records, including complete*
16 *data derived from all tests necessary to ensure*
17 *that the prescription drug is in compliance with*
18 *established specifications and standards.*

19 *“(Q) Documentation demonstrating that the*
20 *testing required by subparagraphs (J) through*
21 *(P) was conducted at a qualifying laboratory in*
22 *the United States.*

23 *“(R) Any other information that the Sec-*
24 *retary determines is necessary to ensure the pro-*
25 *tection of the public health.*

1 “(2) *SECTION 804 IMPORTATION PROGRAM PRO-*
 2 *POSAL.—The regulations under subsection (b) shall*
 3 *require a sponsor of a time-limited section 804 im-*
 4 *portation program authorized under such subsection*
 5 *to submit to the Secretary the following information*
 6 *and documentation in its proposal to the Secretary:*

7 “(A) *The names of all participants in the*
 8 *supply chain, including—*

9 “(i) *the foreign seller;*

10 “(ii) *the importer;*

11 “(iii) *the repackager or relabeler, if*
 12 *different from the importer, that will relabel*
 13 *the eligible prescription drugs; and*

14 “(iv) *the qualifying laboratory that*
 15 *will conduct testing for the importer.*

16 “(B) *Information about how the section 804*
 17 *importation program sponsor will ensure that—*

18 “(i) *the prescription drug meets the*
 19 *testing requirements in subparagraphs (J)*
 20 *through (P) of paragraph (1);*

21 “(ii) *the supply chain is secure;*

22 “(iii) *the prescription drug will meet*
 23 *the labeling requirements of this Act;*

24 “(iv) *the adverse event-related require-*
 25 *ments of this Act are met; and*

1 “(v) the section 804 importation pro-
2 gram will result in a significant reduction
3 in the cost to the American consumer of the
4 prescription drug.

5 “(C) A compliance plan.

6 “(D) Information about how the section 804
7 importation sponsor will ensure that any trade
8 secrets or commercial or financial information
9 that is privileged or confidential that the manu-
10 facturer supplies are kept in strict confidence
11 and used only for the purposes of testing or oth-
12 erwise complying with Federal law.

13 “(3) *PRE -IMPORT REQUEST.*—The regulations
14 under subsection (b) shall require an importer under
15 a program authorized under such subsection to submit
16 a pre-import request to the Secretary at least 30 cal-
17 endar days before the scheduled date of arrival or
18 entry for consumption of a shipment containing a
19 prescription drug covered by the section 804 importa-
20 tion program, whichever is earlier.

21 “(4) *MAINTENANCE BY THE SECRETARY.*—The
22 Secretary shall maintain information and docu-
23 mentation submitted under paragraphs (1), (2), and
24 (3) for such period of time as the Secretary deter-
25 mines to be necessary.

1 “(e) *TESTING.*—*The regulations under subsection (b)*
 2 *shall require—*

3 “(1) *that testing described in subparagraphs (J)*
 4 *through (P) of subsection (d)(1) be conducted by the*
 5 *importer or by the manufacturer of the prescription*
 6 *drug at a qualified laboratory;*

7 “(2) *if the tests are conducted by the importer—*

8 “(A) *that information needed to—*

9 “(i) *authenticate the prescription drug*
 10 *being tested; and*

11 “(ii) *confirm that the labeling of the*
 12 *prescription drug complies with labeling re-*
 13 *quirements under this Act,*

14 *be supplied by the manufacturer of the prescrip-*
 15 *tion drug to the pharmacist or wholesaler; and*

16 “(B) *that the information supplied under*
 17 *subparagraph (A) be kept in strict confidence*
 18 *and used only for purposes of testing or other-*
 19 *wise complying with this Act; and*

20 “(3) *such additional provisions as the Secretary*
 21 *determines to be appropriate to provide for the protec-*
 22 *tion of trade secrets and commercial or financial in-*
 23 *formation that is privileged or confidential.*

24 “(f) *REGISTRATION OF FOREIGN SELLERS.*—*Any es-*
 25 *tablishment within Canada engaged in the distribution of*

1 a prescription drug that is imported or offered for importa-
2 tion into the United States shall register with the Secretary
3 the name and place of business of the establishment and
4 the name of the United States agent for the establishment.

5 “(g) *SUSPENSION OF IMPORTATION.*—The Secretary
6 shall require that importations of a specific prescription
7 drug or importations by a specific importer under sub-
8 section (b) be immediately suspended on discovery of a pat-
9 tern of importation of that specific prescription drug or by
10 that specific importer of drugs that are counterfeit or in
11 violation of any requirement under this section, until an
12 investigation is completed and the Secretary determines
13 that the public is adequately protected from counterfeit and
14 violative prescription drugs being imported under sub-
15 section (b).

16 “(h) *APPROVED LABELING.*—The manufacturer of a
17 prescription drug shall provide an importer written author-
18 ization for the importer to use, at no cost, the approved
19 labeling for the prescription drug.

20 “(i) *CHARITABLE CONTRIBUTIONS.*—Notwithstanding
21 any other provision of this section, section 801(d)(1) con-
22 tinues to apply to a prescription drug that is donated or
23 otherwise supplied at no charge by the manufacturer of the
24 drug to a charitable or humanitarian organization (includ-

1 *ing the United Nations and affiliates) or to a government*
 2 *of a foreign country.*

3 “(j) *IMPORTATION FOR PERSONAL USE.*—

4 “(1) *DECLARATIONS.*—Congress declares that, in
 5 *implementing the provisions under this section, the*
 6 *Secretary may—*

7 “(A) *focus enforcement on cases in which*
 8 *the importation by an individual poses a signifi-*
 9 *cant threat to public health; and*

10 “(B) *exercise discretion to permit individ-*
 11 *uals to make such importations in circumstances*
 12 *in which—*

13 “(i) *the importation is clearly for per-*
 14 *sonal use; and*

15 “(ii) *the prescription drug or device*
 16 *imported does not appear to present an un-*
 17 *reasonable risk to the individual.*

18 “(2) *REGULATIONS.*—

19 “(A) *IN GENERAL.*—The Secretary may, by
 20 *regulation, permit importation of a prescription*
 21 *drug, or class of prescription drugs, for personal*
 22 *use, provided that such importation—*

23 “(i) *does not increase the public’s expo-*
 24 *sure to counterfeit prescription drug prod-*
 25 *ucts;*

1 “(ii) does not pose a risk of creating,
 2 exacerbating, or prolonging an opioid epi-
 3 demic, including by increasing the public’s
 4 exposure to counterfeit prescription opioid
 5 drug products, such as counterfeit fentanyl,
 6 or increasing the public’s misuse of pre-
 7 scription opioid drug products;

8 “(iii) meets the certification require-
 9 ments under subsection (l)(1); and

10 “(iv) meets such other conditions as the
 11 Secretary determines to be appropriate.

12 “(B) REQUIREMENTS.—Regulations de-
 13 scribed in subparagraph (A) may permit impor-
 14 tation into the United States of a prescription
 15 drug that—

16 “(i) is imported in a quantity that
 17 does not exceed a 90-day supply;

18 “(ii) is for personal use by an indi-
 19 vidual, not for resale;

20 “(iii) is accompanied by a copy of a
 21 valid prescription issued by a health care
 22 practitioner licensed by a State to practice
 23 in the United States to administer the drug,
 24 and is not distributed to anyone other than

1 *the individual for whom such prescription*
2 *is written;*

3 “(iv) *is imported from Canada, from a*
4 *licensed pharmacy physically located in*
5 *Canada and registered with the Secretary;*

6 “(v) *is a prescription drug that com-*
7 *plies with section 505 (including with re-*
8 *spect to being safe and effective for the in-*
9 *tended use of the prescription drug), with*
10 *sections 501 and 502, and with other appli-*
11 *cable requirements of this Act;*

12 “(vi) *is accompanied by an electronic*
13 *import entry for such prescription drug re-*
14 *gardless of its values, submitted using an*
15 *authorized electronic data interchange sys-*
16 *tem;*

17 “(vii) *is in the form of a final finished*
18 *dosage that was manufactured in an estab-*
19 *lishment registered under section 510; and*

20 “(viii) *is imported under such other*
21 *conditions as the Secretary determines to be*
22 *necessary to ensure public safety.*

23 “(C) *PROCEDURE.—The Secretary shall—*

24 “(i) *proceed in accordance with section*
25 *553 of title 5 (without regard to any ref-*

1 *erence in such section to sections 556 and*
2 *557 of such title) when promulgating a reg-*
3 *ulation under subparagraph (A), and*
4 *shall—*

5 *“(I) publish a notice of proposed*
6 *rulemaking stating with particularity*
7 *the reason for the proposed rule;*

8 *“(II) allow interested persons to*
9 *submit written data, views, and argu-*
10 *ments, and make all such submissions*
11 *publicly available;*

12 *“(III) hold a public meeting; and*

13 *“(IV) promulgate a final rule*
14 *based on the matter in the rulemaking*
15 *record;*

16 *“(ii) consult with the United States*
17 *Trade Representative, the Commissioner of*
18 *the U.S. Customs and Border Protection,*
19 *and the Administrator of the Drug Enforce-*
20 *ment Administration prior to proposing*
21 *and finalizing a rule under subparagraph*
22 *(A);*

23 *“(iii) include in the preamble to the*
24 *proposed rule under subparagraph (A) a*
25 *clear and complete description of how the*

1 *Secretary made each of the determinations*
2 *in subparagraph (A), including associated*
3 *analyses, assumptions, and information*
4 *sources used to make each such determina-*
5 *tion, and a description of any key limita-*
6 *tions or uncertainties that could affect each*
7 *determination; and*

8 *“(iv) publish the proposed rule and*
9 *final rule under subparagraph (A) in the*
10 *Federal Register and concurrently publish*
11 *the record of the consultations described in*
12 *clause (ii) and the descriptions described in*
13 *clause (iii).*

14 *“(k) CONSTRUCTION.—Nothing in this section limits*
15 *the authority of the Secretary relating to the importation*
16 *of prescription drugs, including the Secretary’s authority*
17 *to refuse admission of a drug under section 801(a), other*
18 *than with respect to section 801(d)(1) as provided in this*
19 *section.*

20 *“(l) EFFECTIVENESS OF SECTION.—*

21 *“(1) COMMENCEMENT OF PROGRAM.—This sec-*
22 *tion shall become effective only if the Secretary cer-*
23 *tifies to Congress that the implementation of this sec-*
24 *tion will—*

1 “(A) pose no additional risk to the public’s
2 health and safety;

3 “(B) result in a significant reduction in the
4 cost of covered products to the American con-
5 sumer; and

6 “(C) be subject to adequate and consistent
7 oversight by the Secretary.

8 “(m) *TERMINATION OF PROGRAM.*—If, after the date
9 that is 1 year after the effective date of the regulations under
10 subsection (b) or (j), the Secretary submits to Congress a
11 certification that, in the option of the Secretary, the benefits
12 of implementation of either or both such subsections do not
13 outweigh any detriment of implementation of such sub-
14 section or subsections and any regulations promulgated
15 thereunder, such subsection or subsections shall cease to be
16 effective as of the date that is 30 days after the date on
17 which the Secretary submits the certification.

18 “(n) *AUTHORIZATION OF APPROPRIATIONS.*—There
19 are authorized to be appropriated such sums as are nec-
20 essary to carry out this section.”.

21 (b) *REQUIREMENT.*—The Secretary of Health and
22 Human Services shall reissue, or amend, as appropriate,
23 the regulations published at part 251 of title 21 of the Code
24 of Federal Regulations pursuant to section 804(b) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)),

1 *as in effect on the day before the date of enactment of this*
2 *Act.*

3 **SEC. 907. IMPROVING INFORMATION TECHNOLOGY SYS-**
4 **TEMS OF THE FOOD AND DRUG ADMINISTRA-**
5 **TION.**

6 (a) *FDA STRATEGIC INFORMATION TECHNOLOGY*
7 *PLAN.*—

8 (1) *IN GENERAL.*—Not later than September 30,
9 2023, and at least every 4 years thereafter, the Sec-
10 retary of Health and Human Services shall develop
11 and submit to the appropriate committees of Congress
12 and post on the website of the Food and Drug Admin-
13 istration, a coordinated information technology stra-
14 tegic plan to modernize the information technology
15 systems of the Food and Drug Administration. Each
16 such report shall be known as the “Food and Drug
17 Administration Strategic Information Technology
18 Plan.”. The first such report may include the Data
19 and Technology Modernization Strategy, as set forth
20 in the letters described in section 101(b) of the Food
21 and Drug Administration Safety and Landmark Ad-
22 vancements Act of 2022.

23 (2) *CONTENT OF STRATEGIC PLAN.*—The Food
24 and Drug Administration Strategic Information
25 Technology Plan under paragraph (1) shall include—

1 (A) agency-wide strategic goals and prior-
2 ities for modernizing the information technology
3 systems of the Food and Drug Administration to
4 maximize the efficiency and effectiveness of such
5 systems for enabling the Food and Drug Admin-
6 istration to fulfill its public health mission;

7 (B) specific activities and strategies for
8 achieving the goals and priorities identified
9 under subparagraph (A), and specific milestones,
10 metrics, and performance measures for assessing
11 progress against the strategic goals and prior-
12 ities in subparagraph (A);

13 (C) specific activities and strategies for im-
14 proving and streamlining internal coordination
15 and communication within the Food and Drug
16 Administration, including for activities and
17 communications related to signals of potential
18 public health concerns;

19 (D) challenges and risks the Food and Drug
20 Administration will face in meeting its strategic
21 goals and priorities, and the activities the Food
22 and Drug Administration will undertake to over-
23 come those challenges and mitigate those risks;

24 (E) the ways in which the Food and Drug
25 Administration will use the plan to guide and

1 *coordinate the projects and activities of the Food*
 2 *and Drug Administration across its offices and*
 3 *centers; and*

4 *(F) a skills inventory, needs assessment, gap*
 5 *analysis, and initiatives to address skills gaps as*
 6 *part of a strategic approach to information tech-*
 7 *nology human capital planning.*

8 *(3) EVALUATION OF PROGRESS.—Each Food and*
 9 *Drug Administration Strategic Information Tech-*
 10 *nology Plan issued pursuant to this subsection, with*
 11 *the exception of the first such Food and Drug Admin-*
 12 *istration Strategic Information Technology Plan,*
 13 *shall include an evaluation of—*

14 *(A) the progress the Secretary has made,*
 15 *based on the metrics, benchmarks, and other*
 16 *milestones that measure successful development*
 17 *and implementation of information technology*
 18 *systems; and*

19 *(B) whether such actions improved the ca-*
 20 *capacity of the Food and Drug Administration to*
 21 *achieve the strategic goals and priorities set forth*
 22 *in the previous Food and Drug Administration*
 23 *Strategic Information Technology Plan.*

24 *(b) GAO REPORT.—*

1 (1) *IN GENERAL.*—Not later than September 30,
 2 2026, the Comptroller General of the United States
 3 shall submit to the Committee on Health, Education,
 4 Labor, and Pensions of the Senate and the Committee
 5 on Energy and Commerce of the House of Representa-
 6 tives a report assessing the implementation of the
 7 Food and Drug Administration Strategic Information
 8 Technology Plan adopted pursuant to subsection (a).

9 (2) *CONTENT OF REPORT.*—The report required
 10 under paragraph (1) shall include an assessment of—

11 (A) the development and implementation of
 12 the Food and Drug Administration Strategic In-
 13 formation Technology Plan, including the suffi-
 14 ciency of the plan, progress of the Food and
 15 Drug Administration in meeting the results-ori-
 16 ented goals, milestones, and performance meas-
 17 ures identified in such plan and any gaps in
 18 such implementation;

19 (B) the efficiency and effectiveness of the
 20 Food and Drug Administration's expenditures
 21 on information technology systems over the pre-
 22 ceding 10 fiscal years, including the implementa-
 23 tion by the Food and Drug Administration of
 24 the Technology Modernization Action Plan and
 25 Data Modernization Action Plan;

1 (C) challenges posed by the information
 2 technology systems of the Food and Drug Admin-
 3 istration for carrying out the Food and Drug
 4 Administration’s public health mission, includ-
 5 ing on meeting user fee agreement performance
 6 goals, conducting inspections, responding to
 7 identified safety concerns, and keeping pace with
 8 new scientific and medical advances; and

9 (D) recommendations for the Food and
 10 Drug Administration to address the identified
 11 challenges, improve its implementation of the
 12 Food and Drug Administration Strategic Infor-
 13 mation Technology Plan, and to otherwise im-
 14 prove the Food and Drug Administration’s infor-
 15 mation technology systems.

16 **SEC. 908. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

17 Section 503 of the Federal Food, Drug, and Cosmetic
 18 Act (21 U.S.C. 353) is amended by adding at the end the
 19 following:

20 “(h) **DEEMING CERTAIN PRODUCTS AS DRUGS.**—

21 “(1) **IN GENERAL.**—Any contrast agent, radio-
 22 active drug, OTC monograph drug, or ophthalmic
 23 drug article shall be deemed to be a drug under sec-
 24 tion 201(g) and not a device under section 201(h).

1 “(2) *DEFINITIONS.*—*For purposes of this sub-*
2 *section—*

3 “(A) *the term ‘contrast agent’ means an ar-*
4 *ticle that is intended for use in conjunction with*
5 *a medical imaging device, and that—*

6 “(i) *is a diagnostic radiopharma-*
7 *ceutical, as defined in section 315.2 and*
8 *601.31 of title 21, Code of Federal Regula-*
9 *tions (or any successor regulations), includ-*
10 *ing PET drugs, as defined in section 212.1*
11 *of title 21, Code of Federal Regulations (or*
12 *any successor regulations) and positron*
13 *emission tomography radiotracers; or*

14 “(ii) *is a diagnostic agent that im-*
15 *proves the visualization of structure or func-*
16 *tion within the body by increasing the rel-*
17 *ative difference in signal intensity within*
18 *the target tissue, structure, or fluid;*

19 “(B) *the term ‘ophthalmic drug article’*
20 *means any eye cup, eye dropper, or other similar*
21 *dispenser intended for ophthalmic use if pack-*
22 *aged with the drug with which such article is in-*
23 *tended to be used;*

1 “(C) the term ‘OTC monograph drug’ has
2 the meaning given such term in section 744L;
3 and

4 “(D) the term ‘radioactive drug’ has the
5 meaning given such term in section 310.3(n) of
6 title 21, Code of Federal Regulations (or any
7 successor regulations), except that such term does
8 not include—

9 “(i) implants or articles similar to an
10 implant;

11 “(ii) articles that apply radiation from
12 outside of the body; or

13 “(iii) the radiation source of an article
14 described in clause (i) or (ii).

15 “(3) *RULE OF CONSTRUCTION.*—Nothing in this
16 subsection shall be construed as allowing for the clas-
17 sification of a product as a drug (as defined in sec-
18 tion 201(g)) if such product—

19 “(A) is not described in paragraph (1); and

20 “(B) meets the definition of a device under
21 section 201(h), unless another provision of this
22 Act otherwise indicates a different classification.

23 “(4) *FEES.*—The Secretary shall waive the ap-
24 plication fee under sections 736 and 744B for appli-
25 cations for products that are, on the date of enact-

1 *ment of the Food and Drug Administration Safety*
 2 *and Landmark Advancements Act of 2022, legally*
 3 *marketed as medical devices and that are deemed*
 4 *drugs pursuant to paragraph (1).”.*

5 **SEC. 909. REPORTING ON MAILROOM AND OFFICE OF THE**
 6 **EXECUTIVE SECRETARIAT OF THE FOOD AND**
 7 **DRUG ADMINISTRATION.**

8 *(a) REPORT.—Not later than 90 days after the date*
 9 *of enactment of this Act, the Secretary of Health and*
 10 *Human Services (referred to in this section as the “Sec-*
 11 *retary”)* shall report to the Committee on Health, Edu-
 12 *cation, Labor, and Pensions of the Senate and the Com-*
 13 *mittee on Energy and Commerce of the House of Represent-*
 14 *atives on—*

15 *(1) information related to policies, procedures,*
 16 *and activities of the mailroom and the Office of the*
 17 *Executive Secretariat of the Food and Drug Adminis-*
 18 *tration, including—*

19 *(A) taking receipt, tracking, managing, and*
 20 *prioritizing confidential informant complaints;*

21 *(B) taking receipt of common carrier pack-*
 22 *ages to the Food and Drug Administration;*

23 *(C) the organizational structure and man-*
 24 *agement of the mailroom;*

1 (D) the organizational structure and man-
2 agement of the Office of the Executive Secre-
3 tariat;

4 (E) the total number of employees and con-
5 tractors in the mailroom including those working
6 remotely and those working in person;

7 (F) the total number of employees and con-
8 tractors in the Office of the Executive Secre-
9 tariat;

10 (G) the number of vacant positions in the
11 mailroom;

12 (H) the number of vacant positions in the
13 Office of the Executive Secretariat;

14 (I) the average number of days for response
15 to correspondence received by the Office of the
16 Secretariat;

17 (J) the extent to which there is a backlog of
18 common carrier packages received by the mail-
19 room and the number of common carrier pack-
20 ages in any backlog;

21 (K) the extent to which there is a backlog of
22 correspondence in the Office of the Executive Sec-
23 retariat that has not been appropriately re-
24 sponded to by the Food and Drug Administra-

1 *tion and the number of correspondence or com-*
2 *mon carrier packages in any backlog;*

3 *(L) a rationale for the failure of the Office*
4 *of the Executive Secretariat to respond to cor-*
5 *respondence in any backlog and the position of*
6 *the decision-making official who determined not*
7 *to respond to such correspondence;*

8 *(M) the number of whistleblower correspond-*
9 *ence received, including within each agency cen-*
10 *ter;*

11 *(N) the amount of resources expended for*
12 *the mailroom, including a breakdown of budget*
13 *authority and user fee dollars;*

14 *(O) the amount of resources expended for*
15 *the Office of the Executive Secretariat and cor-*
16 *respondence-related activities, including a break-*
17 *down of budget authority and user fee dollars;*
18 *and*

19 *(P) the performance of third-party contrac-*
20 *tors responsible for correspondence-related activi-*
21 *ties with respect to the receipt and tracking of*
22 *correspondence, and efforts by the Food and*
23 *Drug Administration to improve performance by*
24 *such contractors; and*

1 (2) *the development and implementation of new*
 2 *or revised policies and procedures of the Food and*
 3 *Drug Administration to monitor and ensure—*

4 (A) *the effective receipt, tracking, man-*
 5 *aging, and prioritization of such complaints;*
 6 *and*

7 (B) *the effective receipt of common carrier*
 8 *packages to the Food and Drug Administration.*

9 (b) *QUARTERLY REPORTING.— Beginning on the date*
 10 *of enactment of this Act, the Secretary shall issue a report*
 11 *each quarter through September 30, 2024, to the Committee*
 12 *on Health, Education, Labor, and Pensions of the Senate*
 13 *and the Committee on Energy and Commerce of the House*
 14 *of Representatives on the implementation of the new or re-*
 15 *vised policies of the Food and Drug Administration re-*
 16 *ported under subsection (a)(2), and since such implementa-*
 17 *tion—*

18 (1) *the volume of incoming common carrier*
 19 *packages to the mailroom;*

20 (2) *the volume of incoming correspondence to the*
 21 *Office of the Executive Secretariat;*

22 (3) *the extent to which new backlogs occur in the*
 23 *processing of common carrier packages received by the*
 24 *mailroom;*

1 (4) *the extent to which new backlogs occur in the*
2 *processing of correspondence received by the Office of*
3 *the Executive Secretariat;*

4 (5) *the length of time required to resolve each*
5 *such backlog;*

6 (6) *any known issues of unreasonable delays in*
7 *correspondence being provided to the intended recipi-*
8 *ent, or in correspondence being lost, and the measures*
9 *taken to remedy such delays or lost items;*

10 (7) *the average number of days it takes to re-*
11 *spond to correspondence received by the Office of the*
12 *Executive Secretariat;*

13 (8) *the resources expended by the mailroom, in-*
14 *cluding a breakdown of budget authority and user fee*
15 *dollars; and*

16 (9) *the resources expended by the Office of the*
17 *Executive Secretariat on correspondence-related ac-*
18 *tivities, including a breakdown of budget authority*
19 *and user fee dollars.*

20 (c) *GAO REPORT.*—*Not later than 18 months after the*
21 *date of enactment of this Act, the Comptroller General of*
22 *the United States shall submit to the Committee on Health,*
23 *Education, Labor, and Pensions of the Senate and the Com-*
24 *mittee on Energy and Commerce of the House of Represent-*
25 *atives a report assessing the policies and practices of the*

1 *Division of Executive Operations of the Office of the Execu-*
 2 *tive Secretariat of the Food and Drug Administration with*
 3 *respect to the receipt, tracking, managing, and*
 4 *prioritization of correspondence.*

5 **SEC. 910. PROTECTING INFANTS AND IMPROVING FORMULA**
 6 **SUPPLY.**

7 (a) *DEFINITIONS.—*

8 (1) *IN GENERAL.—In this section—*

9 (A) *the term “infant formula” has the*
 10 *meaning given such term in section 201 of the*
 11 *Federal Food, Drug, and Cosmetic Act (21*
 12 *U.S.C. 321); and*

13 (B) *the term “Secretary” means the Sec-*
 14 *retary of Health and Human Services.*

15 (2) *CRITICAL FOOD.—Section 201 of the Federal*
 16 *Food, Drug, and Cosmetic Act (21 U.S.C. 321), as*
 17 *amended by section 822, is further amended by add-*
 18 *ing at the end the following:*

19 *“(tt) The term ‘critical food’ means a food that—*

20 *“(1) is an infant formula;*

21 *“(2) is a medical food, as defined in section*
 22 *5(b)(3) of the Orphan Drug Act; or*

23 *“(3) is intended for use by individuals with cer-*
 24 *tain inborn errors of metabolism or other conditions*
 25 *requiring a medical food.”.*

1 (b) *OFFICE OF CRITICAL FOODS.*—

2 (1) *IN GENERAL.*—*The Secretary shall establish*
 3 *within the Center for Food Safety and Applied Nutri-*
 4 *tion an office to be known as the Office of Critical*
 5 *Foods. The Secretary shall appoint a Director to lead*
 6 *such Office.*

7 (2) *DUTIES.*—*The Office of Critical Foods shall*
 8 *be responsible for oversight, coordination, and facili-*
 9 *tation of activities related to critical foods, as defined*
 10 *in section 201(tt) of the Federal Food, Drug, and Cos-*
 11 *metic Act, as added by subsection (a)(2), and any*
 12 *other food determined by the Secretary to be critical.*

13 (c) *PREMARKET SUBMISSIONS OF INFANT FORMULA*
 14 *TO ADDRESS SHORTAGES.*—*Section 412 of the Federal*
 15 *Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended*
 16 *by adding at the end the following:*

17 “(j) *PREMARKET SUBMISSIONS TO ADDRESS SHORT-*
 18 *AGES.*—

19 “(1) *IN GENERAL.*—*The Secretary shall waive*
 20 *the 90 day premarket submission requirement under*
 21 *section 412(c) and apply a 30-day premarket submis-*
 22 *sion requirement, for any person who intends to in-*
 23 *troduce or deliver for introduction into interstate*
 24 *commerce any new infant formula.*

1 “(2) *EFFECTIVE PERIOD.*—*The waiver authority*
 2 *under this subsection shall remain in effect for 90*
 3 *days beginning on the date that the Secretary distrib-*
 4 *utes information under section 424(a)(2), or such*
 5 *longer period as the Secretary determines appropriate*
 6 *to prevent or mitigate a shortage of infant formula.*

7 “(3) *REPORT.*—*Not later than one year after the*
 8 *date of enactment of the Food and Drug Administra-*
 9 *tion Safety and Landmark Advancements Act of*
 10 *2022, the Secretary shall submit a report to the Com-*
 11 *mittee on Health, Education, Labor, and Pensions of*
 12 *the Senate and the Committee on Energy and Com-*
 13 *merce of the House of Representatives that includes—*

14 “(A) *the number of premarket submissions*
 15 *for new infant formula the Secretary has re-*
 16 *ceived under subsection (d) each year since 2012;*

17 “(B) *how many of such submissions re-*
 18 *ceived requests from the Secretary for additional*
 19 *information;*

20 “(C) *how long after receiving such submis-*
 21 *sions the Secretary sent such requests for addi-*
 22 *tional information;*

23 “(D) *what additional information the Sec-*
 24 *retary requested of the persons submitting such*
 25 *submissions; and*

1 “(E) the date each new infant formula
2 product described in subparagraph (A) was first
3 marketed, if available.”.

4 (d) *INFANT FORMULA FLEXIBILITIES.*—The Secretary
5 shall publish a list on the website of the Food and Drug
6 Administration detailing which infant formula products
7 may be appropriate substitutes for infant formula products
8 in shortage that are relied upon by infants and other indi-
9 viduals with amino-acid and metabolic conditions.

10 (e) *INTERNATIONAL HARMONIZATION OF INFANT FOR-*
11 *MULA REQUIREMENTS.*—

12 (1) *IN GENERAL.*—The Secretary—

13 (A) shall participate in meetings with rep-
14 resentatives from other countries to discuss meth-
15 ods and approaches to harmonizing regulatory
16 requirements for infant formula, including with
17 respect to inspections, labeling, and nutritional
18 requirements; and

19 (B) may enter into agreements regarding
20 such requirements with other countries, as ap-
21 propriate.

22 (2) *STUDY ON INFANT FORMULA.*—

23 (A) *IN GENERAL.*—Not later than 60 days
24 after the date of enactment of this Act, the Sec-
25 retary shall seek to enter into an agreement with

1 *the National Academies of Sciences, Engineering,*
2 *and Medicine (referred to in this paragraph as*
3 *the “National Academies”) to examine and re-*
4 *port on challenges in supply, market competi-*
5 *tion, and regulation of infant formula in the*
6 *United States.*

7 (B) *REQUIREMENTS OF FOREIGN COUN-*
8 *TRIES.—The report developed pursuant to the*
9 *agreement under subparagraph (A) shall assess*
10 *and evaluate infant formula marketed in the*
11 *United States, any challenges in supply, market*
12 *competition, and any differences in infant for-*
13 *mula marketed in the European Union, includ-*
14 *ing with respect to nutritional content and ap-*
15 *plicable labeling and other regulatory require-*
16 *ments.*

17 (C) *FINAL REPORT.—The agreement under*
18 *subparagraph (A) shall specify that the National*
19 *Academies shall, not later than 1 year after the*
20 *date of enactment of this Act, complete such*
21 *study and submit a report on the results of such*
22 *study to the Committee on Health, Education,*
23 *Labor, and Pensions of the Senate and the Com-*
24 *mittee on Energy and Commerce of the House of*
25 *Representatives.*

1 (f) *TRANSPARENCY AND ACCOUNTABILITY TO SUPPORT*
 2 *INFANT FORMULA INNOVATION.*—

3 (1) *CONGRESSIONAL NOTIFICATION OF RE-*
 4 *CALL.*—

5 (A) *IN GENERAL.*—*Not later than 24 hours*
 6 *after the initiation of a recall of infant formula*
 7 *as described in section 412(e) of the Federal*
 8 *Food, Drug, and Cosmetic Act (21 U.S.C.*
 9 *350e(e)), the Secretary of Health and Human*
 10 *Services, acting through the Commissioner of*
 11 *Food and Drugs, shall submit to Congress a no-*
 12 *tification of such recall.*

13 (B) *CONTENTS.*—*A notification under sub-*
 14 *paragraph (A) shall include the following:*

15 (i) *If the recall is required by the Food*
 16 *and Drug Administration, a summary of*
 17 *the determination of a case of adulterated*
 18 *or misbranded infant formula that presents*
 19 *a risk to human health.*

20 (ii) *If the recall is voluntarily initi-*
 21 *ated by the manufacturer, a summary of the*
 22 *information provided to the Food and Drug*
 23 *Administration by the manufacturer re-*
 24 *garding infant formula that has left the*

control of the manufacturer that may be adulterated or misbranded.

(iii) *Specification of when the Food and Drug Administration was first made aware of the instance or circumstances surrounding the recall.*

(iv) *An initial estimate of the disruption in domestic production that may result from the recall.*

(2) *ANNUAL REPORT TO CONGRESS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by subsection (c), is further amended by adding at the end the following:*

“(k) ANNUAL REPORT TO CONGRESS.—

“(1) IN GENERAL.—Not later than March 30 of each year, the Secretary shall submit a report to Congress containing, with respect to the preceding calendar year, the following information:

“(A) The number of submissions received by the Secretary under subsection (d).

“(B) The number of submissions that included any new ingredients that were not included in any infant formula already on the market.

1 “(C) *The number of inspections conducted*
2 *by the Food and Drug Administration or any*
3 *agent thereof to evaluate compliance with the re-*
4 *quirements for infant formulas under subsection*
5 *(b)(2).*

6 “(D) *The time between any inspection re-*
7 *ferred to in subparagraph (C) and any necessary*
8 *reinspection to evaluate compliance with the re-*
9 *quirements for infant formulas under subsection*
10 *(b)(2).*

11 “(E) *A breakdown of the information de-*
12 *scribed in subparagraphs (A) through (D) be-*
13 *tween foreign and domestic manufacturers and*
14 *facilities.*

15 “(2) *CONFIDENTIALITY.—The Secretary shall en-*
16 *sure that the reports under paragraph (1) do not in-*
17 *clude any information that is a trade secret or con-*
18 *fidential information subject to section 552(b)(4) of*
19 *title 5, United States Code, or section 1905 of title 18,*
20 *United States Code.”.*

21 “(3) *MARKETING SUBMISSIONS.—Section 412 of*
22 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
23 *350a), as amended by paragraph (2), is further*
24 *amended by adding at the end the following:*

25 “(l) *MARKETING SUBMISSIONS.—*

1 “(1) *IN GENERAL.*—Subject to paragraph (2), the
 2 Secretary shall respond to a submission under sub-
 3 section (d) for infant formula not later than 65 days
 4 after receiving such submission.

5 “(2) *EXPEDITED RESPONSE.*—The Secretary
 6 shall respond to a submission under subsection (d) for
 7 infant formula not later than 45 days after receiving
 8 such notification if it—

9 “(A) is submitted by a manufacturer that is
 10 not already marketing infant formula in the
 11 United States; or

12 “(B) is a new infant formula, as defined in
 13 subsection (c)(2).”.

14 “(4) *LIST OF NUTRIENTS.*—Section 412(i)(1) of
 15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 16 350a(i)) is amended by striking “or, if revised by the
 17 Secretary under paragraph (3), as so revised” and in-
 18 serting the following: “, which shall be reviewed by
 19 the Secretary every 4 years as appropriate. In review-
 20 ing such table, the Secretary shall consider any new
 21 scientific data or information related to infant for-
 22 mula nutrients, including international infant for-
 23 mula standards. The Secretary may revise the list of
 24 nutrients and the required level for any nutrient re-
 25 quired by the table”.

1 (5) *TECHNICAL CORRECTION.—Section*
 2 *412(c)(1)(B) of the Federal Food, Drug, and Cosmetic*
 3 *Act (21 U.S.C. 350a(c)(1)(B)) is amended by striking*
 4 *“subsection (c)(1)” and inserting “subsection (d)(1)”.*
 5 *(g) RESPONSE TO RECALL.—*

6 (1) *MANUFACTURER SUBMISSION.—*

7 (A) *IN GENERAL.—Promptly after the initi-*
 8 *ation of a recall of infant formula, the manufac-*
 9 *turer of the recalled infant formula shall submit*
 10 *information to the Secretary regarding such re-*
 11 *call.*

12 (B) *CONTENTS.—A submission under sub-*
 13 *paragraph (A) shall include the following:*

14 (i) *A plan (including an estimated*
 15 *timeline, as applicable) of actions the man-*
 16 *ufacturer will take, suited to the individual*
 17 *circumstances of the particular recall, in-*
 18 *cluding—*

19 (I) *to identify and address any*
 20 *cause of adulteration or misbranding;*
 21 *and*

22 (II) *if appropriate, to restore op-*
 23 *eration of the impacted facilities.*

24 (ii) *In the case that a recall of the*
 25 *manufacturer’s infant formula products,*

1 *and subsequent actions to respond to such*
 2 *recall, impacts over 10 percent of the pro-*
 3 *duction of the infant formula intended for*
 4 *sale in the United States, a plan to backfill*
 5 *the supply of the manufacturer's infant for-*
 6 *mula supply if the current domestic supply*
 7 *of such infant formula has fallen, or is ex-*
 8 *pected to fall, below the expected demand for*
 9 *the formula.*

10 (2) *REPORT TO CONGRESS.—*

11 (A) *IN GENERAL.—Promptly after a sub-*
 12 *mission under paragraph (1) is received, the*
 13 *Secretary shall provide such submission, together*
 14 *with the information specified in subparagraph*
 15 *(B), in a report to the Committee on Health,*
 16 *Education, Labor, and Pensions of the Senate*
 17 *and the Committee on Energy and Commerce of*
 18 *the House of Representatives.*

19 (B) *CONTENTS.—A submission under sub-*
 20 *paragraph (A) shall include the following:*

21 (i) *Information concerning the current*
 22 *domestic supply of infant formula, includ-*
 23 *ing—*

24 (I) *a breakdown of the specific*
 25 *types of formula involved; and*

1 (II) *an estimate of how long cur-*
 2 *rent supplies will last.*

3 (ii) *In the case that a submission or*
 4 *submissions under paragraph (1) show that*
 5 *the recall and subsequent actions to respond*
 6 *to the recall impact over 10 percent of the*
 7 *domestic production of infant formula in-*
 8 *tended for sale in the United States—*

9 (I) *actions to work with the im-*
 10 *pacted manufacturer or other manufac-*
 11 *turers to increase production; and*

12 (II) *specification of—*

13 (aa) *any additional authori-*
 14 *ties needed regarding production*
 15 *or importation to fill a supply*
 16 *gap; and*

17 (bb) *any supplemental fund-*
 18 *ing necessary to address the short-*
 19 *age.*

20 (3) *SUNSET.—This subsection shall cease to have*
 21 *force or effect on of September 30, 2026.*

22 (h) *COORDINATION WITH MANUFACTURER.—*

23 (1) *IN GENERAL.—*

24 (A) *COMMUNICATION FOLLOWING INSPEC-*
 25 *TION.—Upon completing an inspection of an in-*

1 *fant formula manufacturing facility impacted by*
 2 *a recall, the Secretary, acting through the Com-*
 3 *missioner of Food and Drugs, shall provide the*
 4 *manufacturer involved a list of any actions nec-*
 5 *essary to—*

6 *(i) address deficiencies contributing to*
 7 *the potential adulteration or misbranding of*
 8 *product at the facility; and*

9 *(ii) safely restart production at the fa-*
 10 *cility.*

11 *(B) RESPONSE TO MANUFACTURER.—Not*
 12 *later than 7 days after receiving a written com-*
 13 *munication from a manufacturer of infant for-*
 14 *mula regarding safely restoring production fol-*
 15 *lowing a recall of such product, the Secretary,*
 16 *acting through the Commissioner of Food and*
 17 *Drugs, shall provide a substantive response to*
 18 *such communication, including any necessary*
 19 *next steps.*

20 *(2) INSPECTIONS.—The Secretary shall ensure*
 21 *timely communication with a manufacturer of infant*
 22 *formula following an inspection of a facility engaged*
 23 *in the manufacturing of infant formula for consump-*
 24 *tion in the United States. If a reinspection of a man-*
 25 *ufacturer of an infant formula is required to ensure*

1 *that such manufacturer completed any remediation*
 2 *actions or addressed any deficiencies, the Secretary*
 3 *shall reinspect such facility in a timely manner. The*
 4 *Secretary shall prioritize and expedite an inspection*
 5 *or reinspection of an establishment that could help*
 6 *mitigate or prevent a shortage of an infant formula.*

7 (3) *ANNUAL INSPECTIONS.*—*Not later than 6*
 8 *months after the date of enactment of this Act, and*
 9 *not less than once per calendar year thereafter, the*
 10 *Secretary shall conduct inspections, including unan-*
 11 *nounced inspections, of the facilities (including for-*
 12 *foreign facilities) of each manufacturer of an infant for-*
 13 *mula required to be registered under section*
 14 *412(c)(1)(A) of the Federal Food, Drug, and Cosmetic*
 15 *Act (21 U.S.C. 350a(c)(1)(A)), in accordance with a*
 16 *risk based approach and ensure timely and effective*
 17 *internal coordination and alignment among the in-*
 18 *vestigators and the Center for Food Safety and Ap-*
 19 *plied Nutrition.*

20 (i) *NATIONAL STRATEGY ON INFANT FORMULA.*—

21 (1) *IN GENERAL.*—*The Secretary, in consultation*
 22 *with the Secretary of Agriculture and other heads of*
 23 *relevant departments and agencies, shall develop and*
 24 *issue, not later than 90 days after the date of enact-*
 25 *ment of this Act, a national strategy on infant for-*

1 *mula to increase the resiliency of the infant formula*
 2 *supply chain, protect against future contamination*
 3 *and other potential causes of shortages, and ensure*
 4 *parents and caregivers have access to formula and in-*
 5 *formation they need.*

6 (2) *NATIONAL STRATEGY.—The national strategy*
 7 *under paragraph (1) shall—*

8 (A) *increase the resiliency of the infant for-*
 9 *mula supply chain in the short-term by—*

10 (i) *assessing causes of the current*
 11 *shortage and potential causes of future*
 12 *shortages,*

13 (ii) *assessing and addressing imme-*
 14 *diate infant formula needs associated with*
 15 *the shortage, and*

16 (iii) *developing a plan to increase in-*
 17 *fant formula supply, including through in-*
 18 *creased competition;*

19 (B) *improve preparedness against infant*
 20 *formula shortages in the long-term by—*

21 (i) *outlining methods to improve infor-*
 22 *mation-sharing between the Federal Govern-*
 23 *ment and State and local governments, and*
 24 *other entities as appropriate, regarding*
 25 *shortages;*

1 (ii) recommending measures for pro-
 2 tecting the integrity of infant formula sup-
 3 ply and preventing contamination;

4 (iii) outlining methods to incentivize
 5 new infant formula manufacturers to in-
 6 crease supply and mitigate future shortages;
 7 and

8 (iv) recommending other necessary au-
 9 thorities to gain insight into the supply
 10 chain and risk for shortages, and to
 11 incentivize new infant formula manufactur-
 12 ers; and

13 (C) ensure the development and updating of
 14 education and communication materials for par-
 15 ents and caregivers that cover—

16 (i) where and how to find infant for-
 17 mula;

18 (ii) comparable infant formulas on the
 19 market,

20 (iii) what to do if a medical or spe-
 21 cialty infant formula is unavailable;

22 (iv) safe practices for handling infant
 23 formula; and

24 (v) other topics, as appropriate.

1 (j) *MEANINGFUL DISRUPTION IN THE PRODUCTION OF*
 2 *CRITICAL FOOD.*—Chapter IV of the Federal Food, Drug,
 3 and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by
 4 adding at the end the following:

5 **“SEC. 424. REQUIREMENTS FOR CRITICAL FOOD.**

6 “(a) *NOTIFICATION OF MEANINGFUL DISRUPTION FOR*
 7 *CRITICAL FOOD.*—

8 “(1) *IN GENERAL.*—A manufacturer of a critical
 9 food (as defined in section 201(tt)) shall notify the
 10 Secretary of a permanent discontinuance in the man-
 11 ufacture or an interruption of the manufacture of
 12 such food that is likely to lead to a meaningful dis-
 13 ruption in the supply of such food in the United
 14 States, and the reasons for such discontinuance or
 15 interruption, as soon as practicable, but not later
 16 than 5 business days after such discontinuance or
 17 such interruption.

18 “(2) *DISTRIBUTION OF INFORMATION.*—Not later
 19 than 5 calendar days after receiving a notification
 20 under paragraph (1), the Secretary shall distribute, to
 21 the Secretary of Agriculture and to the maximum ex-
 22 tent practicable to the appropriate entities, as deter-
 23 mined by the Secretary through such means as the
 24 Secretary determines appropriate, information on the

1 *meaningful disruption of a critical food reported*
 2 *under this subsection.*

3 “(3) *CONFIDENTIALITY.*—*Nothing in this sub-*
 4 *section authorizes the Secretary to disclose any infor-*
 5 *mation that is a trade secret or confidential informa-*
 6 *tion subject to section 552(b)(4) of title 5, United*
 7 *States Code, or section 1905 of title 18, United States*
 8 *Code.*

9 “(4) *MEANINGFUL DISRUPTION.*—*In this sub-*
 10 *section, the term ‘meaningful disruption’—*

11 “(A) *means a change in production that is*
 12 *reasonably likely to lead to a significant reduc-*
 13 *tion in the supply of a critical food by a manu-*
 14 *facturer that affects the ability of the manufac-*
 15 *turer to meet expected demand for its product;*
 16 *and*

17 “(B) *does not include interruptions in man-*
 18 *ufacturing due to matters such as routine main-*
 19 *tenance or insignificant changes in manufac-*
 20 *turing so long as the manufacturer expects to re-*
 21 *sume operations in a short period of time.*

22 “(b) *RISK MANAGEMENT PLANS.*—*Each manufacturer*
 23 *of a critical food shall develop, maintain, and implement,*
 24 *as appropriate, a redundancy risk management plan that*
 25 *identifies and evaluates risks to the supply of the food, as*

1 applicable, for each establishment in which such food is
 2 manufactured. A risk management plan under this sub-
 3 section—

4 “(1) may identify and evaluate risks to the sup-
 5 ply of more than one critical food, or critical food
 6 category, manufactured at the same establishment;
 7 and

8 “(2) shall be subject to inspection and copying
 9 by the Secretary pursuant to an inspection under sec-
 10 tion 704.

11 “(c) *FAILURE TO MEET REQUIREMENTS.*—

12 “(1) *IN GENERAL.*—If a person fails to submit
 13 information required under, and in accordance with,
 14 subsection (a)—

15 “(A) the Secretary shall issue a letter to
 16 such person informing such person of such fail-
 17 ure; and

18 “(B) not later than 45 calendar days after
 19 the issuance of a letter under subparagraph (A),
 20 subject to paragraph (2), the Secretary shall
 21 make available to the public on the website of the
 22 Food and Drug Administration, with appro-
 23 priate redactions made to protect the informa-
 24 tion described in subsection (a)(3)—

1 “(i) the letter issued under subpara-
2 graph (A); and

3 “(ii) at the request of such person, any
4 response to such letter such person sub-
5 mitted to the Secretary.

6 “(2) *EXCEPTION.*—If the Secretary determines
7 that the letter under paragraph (1) was issued in
8 error or, after review of such response, the person had
9 a reasonable basis for not submitting a notification as
10 required under subsection (m), the requirements of
11 paragraph (1)(B) shall not apply.”.

12 (k) *SPECIALTY INFANT FORMULA FOR IMPORTA-*
13 *TION.*—Section 412 of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 350a), as amended by subsection
15 (f)(2), is further amended by adding at the end the fol-
16 lowing:

17 “(m) *WAIVER OF REQUIREMENTS FOR IMPORTATION*
18 *OF SPECIALTY INFANT FORMULA.*—

19 “(1) *IN GENERAL.*—The Secretary may, during
20 a shortage of specialty infant formula as determined
21 by the Secretary, waive any requirement under this
22 Act applicable to facilitate the importation of spe-
23 cialty infant formula. Such a waiver may be applica-
24 ble to—

1 “(A) the importation of specialty infant for-
 2 mula from any country that is determined by
 3 the Secretary to be implementing and enforcing
 4 requirements for infant formula that provide a
 5 similar assurance of safety as the regulatory re-
 6 quirements of this Act; or

7 “(B) the distribution and sale of such im-
 8 ported specialty infant formula.

9 “(2) *RULE OF CONSTRUCTION.*—Nothing in
 10 paragraph (1) shall be construed to limit the author-
 11 ity of the Secretary to require a recall of, or otherwise
 12 impose restrictions and requirements under this Act
 13 with respect to, specialty infant formula that is sub-
 14 ject to a waiver under paragraph (1).

15 “(3) *DEFINITION OF SPECIALTY INFANT FOR-*
 16 *MULA.*—In this subsection, the term ‘specialty infant
 17 formula’ means infant formula, including amino
 18 acid-based formula, intended for use by individuals
 19 who have inborn errors of metabolism or low birth
 20 weight, or who otherwise have unusual medical or di-
 21 etary problems.”.

22 (1) *IMPORTATION FOR PERSONAL USE.*—

23 (1) *IN GENERAL.*—Notwithstanding any other
 24 provision of law, during the 90-day period beginning
 25 on the date of enactment of this Act, a person may,

1 *without prior notice to the Food and Drug Adminis-*
2 *tration, import up to a 3-month supply of infant for-*
3 *mula for personal use from—*

4 *(A) Canada;*

5 *(B) any country in the European Union; or*

6 *(C) any other country that is determined by*
7 *the Secretary, acting through the Commissioner*
8 *of Food and Drugs, to have safety standards for*
9 *infant formula similar to such standards appli-*
10 *cable under the Federal Food, Drug, and Cos-*
11 *metic Act (21 U.S.C. 301 et seq.).*

12 *(2) LIMITATIONS.—Infant formula may be im-*
13 *ported pursuant to paragraph (1) only if the infant*
14 *formula—*

15 *(A) is exclusively for personal use and will*
16 *not be commercialized or promoted; and*

17 *(B) does not present an unreasonable risk to*
18 *human health.*

19 *(3) REPORTING OF ADVERSE EVENTS.—If a*
20 *health care provider becomes aware of any adverse*
21 *event which the health care provider reasonably sus-*
22 *pects to be associated with infant formula imported*
23 *pursuant to paragraph (1), the health care provider*
24 *shall report such adverse event to the Commissioner*
25 *of Food and Drugs.*

1 (4) *PUBLIC NOTICE.*—*The Secretary, acting*
 2 *through the Commissioner of Food and Drugs, shall*
 3 *post on the public website of the Food and Drug Ad-*
 4 *ministration notice that—*

5 (A) *infant formula imported pursuant to*
 6 *paragraph (1) may not have been manufactured*
 7 *in a facility that has been inspected by the Food*
 8 *and Drug Administration;*

9 (B) *the labeling of such infant formula may*
 10 *not meet the standards and other requirements*
 11 *applicable with respect to infant formula under*
 12 *the Federal Food, Drug, and Cosmetic Act (21*
 13 *U.S.C. 301 et seq.); and*

14 (C) *the nutritional content of the infant for-*
 15 *mula may vary from that of infant formula*
 16 *meeting such standards and other requirements.*

17 (5) *SENSE OF CONGRESS.*—*It is the sense of*
 18 *Congress that persons considering the personal impor-*
 19 *tation of infant formula should consult with their pe-*
 20 *diatrician about such importation.*

21 **SEC. 911. PREDETERMINED CHANGE CONTROL PLANS FOR**
 22 **DEVICES.**

23 (a) *IN GENERAL.*—*Chapter V of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended*

1 *by inserting after section 515B (21 U.S.C. 360e-3) the fol-*
 2 *lowing:*

3 **“SEC. 515C. PREDETERMINED CHANGE CONTROL PLANS**
 4 **FOR DEVICES.**

5 “(a) *APPROVED DEVICES.*—

6 “(1) *IN GENERAL.*—*Notwithstanding section*
 7 *515(d)(5)(A), a supplemental application shall not be*
 8 *required for a change to a device approved under sec-*
 9 *tion 515, if such change is consistent with a predeter-*
 10 *mined change control plan that is approved pursuant*
 11 *to paragraph (2).*

12 “(2) *PREDETERMINED CHANGE CONTROL*
 13 *PLAN.*—*The Secretary may approve a predetermined*
 14 *change control plan submitted in an application, in-*
 15 *cluding a supplemental application, under section*
 16 *515 that describes planned changes that may be made*
 17 *to the device (and that would otherwise require a sup-*
 18 *plemental application under section 515), if the de-*
 19 *vice remains safe and effective without any change.*

20 “(3) *SCOPE.*—*The Secretary may require that a*
 21 *change control plan include labeling required for safe*
 22 *and effective use of the device as such device changes*
 23 *pursuant to such plan, notification requirements if*
 24 *the device does not function as intended pursuant to*

1 *such plan, and performance requirements for changes*
2 *made under the plan.*

3 “(b) *CLEARED DEVICES.*—

4 “(1) *IN GENERAL.*—*Notwithstanding section*
5 *510(k), a premarket notification shall not be required*
6 *for a change to a device cleared under section 510(k),*
7 *if such change is consistent with an established pre-*
8 *determined change control plan granted pursuant to*
9 *paragraph (2).*

10 “(2) *PREDETERMINED CHANGE CONTROL*
11 *PLAN.*—*The Secretary may clear a predetermined*
12 *change control plan submitted in a notification sub-*
13 *mitted under section 510(k) that describes planned*
14 *changes that may be made to the device (and that*
15 *would otherwise require a new notification), if—*

16 “(A) *the device remains safe and effective*
17 *without any such change; and*

18 “(B) *the device would remain substantially*
19 *equivalent to the predicate.*

20 “(3) *SCOPE.*—*The Secretary may require that a*
21 *change control plan include labeling required for safe*
22 *and effective use of the device as such device changes*
23 *pursuant to such plan, notification requirements if*
24 *the device does not function as intended pursuant to*

1 *such plan, and performance requirements for changes*
 2 *made under the plan.*

3 “(c) *PREDICATE DEVICES.*—*In making a determina-*
 4 *tion of substantial equivalence pursuant to section 513(i),*
 5 *the Secretary shall not compare a device to changed versions*
 6 *of a device implemented in accordance with an established*
 7 *predetermined change control plan as a predicate device.*
 8 *Only the version of the device cleared or approved, prior*
 9 *to changes made under the predetermined change control*
 10 *plan, may be used by a sponsor as a predicate device.”.*

11 (b) *CONFORMING AMENDMENTS.*—

12 (1) *CLEARED DEVICES.*—*Section 510(l)(1) of the*
 13 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 14 *360(l)(1)) is amended, in the first sentence, by insert-*
 15 *ing “, or with respect to a change that is consistent*
 16 *with a predetermined change control plan cleared*
 17 *under section 515C” before the period at the end.*

18 (2) *APPROVED DEVICES.*—*Section*
 19 *515(d)(5)(A)(i) of the Federal Food, Drug, and Cos-*
 20 *metic Act (21 U.S.C. 360e(d)(5)(A)(i)) is amended by*
 21 *striking “A supplemental” and inserting “Unless the*
 22 *change is consistent with a predetermined change con-*
 23 *trol plan approved under section 515C, a supple-*
 24 *mental”.*

1 (3) *DOCUMENTATION OF RATIONALE FOR SIG-*
 2 *NIFICANT DECISIONS.*—Section 517A(a)(1) of the Fed-
 3 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 360g-*
 4 *1(a)(1)) is amended to read as follows:*

5 “(1) *IN GENERAL.*—The Secretary shall provide
 6 *a substantive summary of the scientific and regu-*
 7 *latory rationale for any significant decision of the*
 8 *Center for Devices and Radiological Health regarding*
 9 *submission or review of a report under section 510(k),*
 10 *a petition for classification under section 513(f), an*
 11 *application under section 515, or an application for*
 12 *an exemption under section 520(g), including docu-*
 13 *mentation of significant controversies or differences of*
 14 *opinion and the resolution of such controversies or*
 15 *differences of opinion.”.*

16 **SEC. 912. PROHIBITION AGAINST FOOD PACKAGING CON-**
 17 **TAINING INTENTIONALLY ADDED PFAS.**

18 (a) *IN GENERAL.*—Section 301 of the *Federal Food,*
 19 *Drug, and Cosmetic Act (21 U.S.C. 331), as amended by*
 20 *section 824(a), is further amended by adding at the end*
 21 *the following:*

22 “(mmm)(1) *The introduction or delivery for introduc-*
 23 *tion into interstate commerce of food packaging containing*
 24 *intentionally added PFAS.*

1 “(2) *The term ‘PFAS’ means a perfluoroalkyl sub-*
 2 *stance or a polyfluoroalkyl substance that is man-made*
 3 *with at least 1 fully fluorinated carbon atom.’”.*

4 (b) *APPLICABILITY.—The amendment made by sub-*
 5 *section (a) applies beginning on January 1, 2024.*

6 **SEC. 913. REQUIREMENTS REGARDING CONFLICTS OF IN-**
 7 **TEREST.**

8 (a) *ONGOING REPORTING OF CONTRACTOR CONFLICTS*
 9 *OF INTEREST.—*

10 (1) *IN GENERAL.—The Secretary of Health and*
 11 *Human Services (referred to in this section as the*
 12 *“Secretary”) shall require entities that contract with*
 13 *the Food and Drug Administration—*

14 (A) *to disclose, on an ongoing basis during*
 15 *the term of the contract, any information related*
 16 *to potential and actual conflicts of interest, in-*
 17 *cluding conflicts of interest concerning the con-*
 18 *tractor’s personnel, consultants, and subcontract-*
 19 *tors; and*

20 (B) *during the term of the contract, to re-*
 21 *frain from entering into consulting or other con-*
 22 *tractual arrangements with any person to per-*
 23 *form work that may reasonably create a poten-*
 24 *tial or actual conflict of interest, without receiv-*
 25 *ing the written approval of the contracting offi-*

1 *cer before the execution of the contractual ar-*
 2 *range ment.*

3 (2) *REGULATIONS.*—*Not later than 18 months*
 4 *after the date of enactment of this Act, the Secretary,*
 5 *in consultation with the Federal Acquisition Regu-*
 6 *latory Council, shall issue regulations to carry out*
 7 *paragraph (1).*

8 (b) *RESTRICTIONS ON FDA CONTRACTORS.*—

9 (1) *PROHIBITION AGAINST CERTAIN CON-*
 10 *TRACTS.*—

11 (A) *IN GENERAL.*—*Subject to subparagraph*
 12 *(B), the Secretary shall not award a contract re-*
 13 *lating to the duties of the Food and Drug Ad-*
 14 *ministration to any person providing consulting*
 15 *services (referred to in this subsection as a “con-*
 16 *sulting firm”)* unless such contract provides that,
 17 *during the restricted period described in sub-*
 18 *paragraph (C), subject to subparagraph (B), no*
 19 *individual employee or subcontractor of such*
 20 *consulting firm may provide services to both—*

21 (i) *the Food and Drug and Adminis-*
 22 *tration under the consulting firm’s contract;*
 23 *and*

1 (ii)(I) *a person engaged in the develop-*
2 *ment or manufacturing of a device, drug, or*
3 *biological product; or*

4 (II) *any other private entity engaged*
5 *in activities regulated by the Food and*
6 *Drug Administration.*

7 (B) *EXCEPTION.—*

8 (i) *IN GENERAL.—The Secretary may*
9 *issue an exception to the requirement under*
10 *subparagraph (A) with respect to an em-*
11 *ployee or subcontractor of a consulting firm*
12 *only if the Secretary or designee determines*
13 *in writing that there is a compelling reason*
14 *to award a contract with such consulting*
15 *firm with such exception. The Secretary*
16 *shall not delegate the authority to issue ex-*
17 *ceptions under this clause below the level of*
18 *head of a contracting activity.*

19 (ii) *REPORTING.—Not later than 14*
20 *days after issuing an exception under clause*
21 *(i), the Secretary shall publish, on the*
22 *website of the Food and Drug Administra-*
23 *tion, a notification of the exception. Such*
24 *notification shall be made publicly available*

1 *in an easily accessible format, and shall in-*
2 *clude—*

3 *(I) the name of the contract;*

4 *(II) the consulting firm receiving*
5 *the exception, and the employee or sub-*
6 *contractor to whom the exception ap-*
7 *plies;*

8 *(III) the other contracts or clients*
9 *that would, in the absence of the excep-*
10 *tion, cause the consulting firm to be in*
11 *violation of subparagraph (A); and*

12 *(IV) the efforts that the consulting*
13 *firm plans to take to mitigate any po-*
14 *tential or actual conflict of interest*
15 *arising from the other work of its em-*
16 *ployees or subcontractors.*

17 *(C) RESTRICTED PERIOD.—*

18 *(i) IN GENERAL.—For purposes of sub-*
19 *paragraph (A), the restricted period is the*
20 *period that—*

21 *(I) begins when the applicable em-*
22 *ployee or subcontractor of the con-*
23 *sulting firm first provides services*
24 *under the consulting firm’s contract;*
25 *and*

1 (ii) ends not less than the appli-
 2 cable period specified in clause (ii)
 3 after the last date on which such em-
 4 ployee or subcontractor provides serv-
 5 ices under the consulting firm's con-
 6 tract.

7 (ii) *APPLICABLE PERIOD SPECIFIED.*—
 8 For purposes of clause (i)(II), the applicable
 9 period specified in this clause is—

10 (I) 30 days; or
 11 (II) such longer period of time as
 12 the Secretary may specify after con-
 13 sultation with the Federal Acquisition
 14 Regulatory Council, which shall apply
 15 with respect to all exceptions issued
 16 under subparagraph (B).

17 (2) *REGULATIONS.*—Not later than 18 months
 18 after the date of enactment of this Act, the Secretary,
 19 in consultation with the Federal Acquisition Regu-
 20 latory Council, shall issue regulations to carry out
 21 paragraph (1).

22 (c) *REQUIREMENTS REGARDING WAIVERS RELATING*
 23 *TO ORGANIZATIONAL CONFLICTS OF INTEREST.*—

24 (1) *IN GENERAL.*—The Secretary shall, not later
 25 than 14 days after awarding a contract relating to

1 *the Food and Drug Administration, publish, on the*
 2 *website of the Food and Drug Administration, a noti-*
 3 *fication of any waiver of any requirements regarding*
 4 *a potential or actual organizational conflict of inter-*
 5 *est granted to the contractor. Such notification shall*
 6 *be made publicly available in an easily accessible for-*
 7 *mat, and shall include the name of the contract, the*
 8 *contractor receiving the waiver, the other contracts or*
 9 *clients that created the potential or actual organiza-*
 10 *tional conflict of interest, and the efforts that the con-*
 11 *tractor plans to take to mitigate the potential or ac-*
 12 *tual organizational conflict of interest.*

13 (2) *REGULATIONS.—Not later than 18 months*
 14 *after the date of enactment of this Act, the Secretary,*
 15 *in consultation with the Federal Acquisition Regu-*
 16 *latory Council, shall issue regulations to carry out*
 17 *paragraph (1).*

18 **SEC. 914. THIRD PARTY DATA TRANSPARENCY.**

19 (a) *IN GENERAL.—To the extent the Secretary of*
 20 *Health and Human Services (referred to in this section as*
 21 *the “Secretary”) seeks to rely on any data, analysis, or*
 22 *other information or findings provided by entities that has*
 23 *been funded in whole or in part by, or otherwise performed*
 24 *under contract with, the Food and Drug Administration,*

1 *in regulatory decision-making with respect to devices, the*
2 *Secretary shall—*

3 (1) *request access to the datasets, inputs, clinical*
4 *or other assumptions, methods, analytical code, re-*
5 *sults, and other components underlying or comprising*
6 *the analysis, conclusions, or other findings upon*
7 *which the Secretary seeks to rely; and*

8 (2) *in the event that information described in*
9 *paragraph (1) is used to support regulatory decision-*
10 *making, and as otherwise appropriate, to the extent*
11 *practicable, provide the manufacturer or manufactur-*
12 *ers subject to such decision a summary of such infor-*
13 *mation, subject to protection of confidential commer-*
14 *cial information or trade secret information or per-*
15 *sonally identifiable information.*

16 (b) *REPORT.—Not later than September 30, 2023, and*
17 *biennially thereafter, the Secretary shall submit to the Com-*
18 *mittee on Health, Education, Labor, and Pensions of the*
19 *Senate and the Committee on Energy and Commerce of the*
20 *House of Representatives, and publish on the website of the*
21 *Food and Drug Administration, a report on the number*
22 *of postmarket device signals communications issued by the*
23 *Secretary, the sources of data for such signals, and how such*
24 *signals were revised or resolved.*

1 **SEC. 915. BANNED DEVICES.**

2 (a) *IN GENERAL.*—Section 516 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360f) is amended—

4 (1) in subsection (a)—

5 (A) in paragraph (1), by inserting “for one
6 or more of its intended uses” before the semi-
7 colon; and

8 (B) in the flush text following paragraph
9 (2), by inserting “for any such intended use or
10 uses” before the period; and

11 (2) by adding at the end the following:

12 “(c) *SPECIFIC DEVICES.*—Adverse conditioning de-
13 vices, including electrical stimulation devices, that apply
14 a noxious electrical stimulation to an individual’s skin in-
15 tended to reduce or cease self-injurious or aggressive behav-
16 ior are deemed to be banned devices, as described in sub-
17 section (a), without the need for the Secretary to promulgate
18 a regulation with respect to such devices as described in
19 such subsection.”.

20 (b) *RULE OF CONSTRUCTION.*—Nothing in this section
21 shall be construed to limit the authority of the Secretary
22 of Health and Human Services to amend, in accordance
23 with section 516 of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360f) and chapter 5 of title 5, United States
25 Code, regulations promulgated pursuant to such section
26 516.

1 **SEC. 916. DEVICE CYBERSECURITY.**

2 (a) *GUIDANCE FOR INDUSTRY AND FDA STAFF ON*
3 *DEVICE CYBERSECURITY.*—Not later than 2 years after the
4 date of enactment of this Act, and periodically thereafter
5 as appropriate, the Secretary of Health and Human Serv-
6 ices (referred to in this section as the “Secretary”), in con-
7 sultation with the Director of the Cybersecurity and Infra-
8 structure Security Agency, shall review and, as appropriate
9 and after soliciting and receiving feedback from device man-
10 ufacturers, health care providers, third party device
11 servicers, patient advocates, and other appropriate stake-
12 holders, update the guidance entitled “Content of Premarket
13 Submissions for Management of Cybersecurity in Medical
14 Devices” (or a successor document).

15 (b) *RESOURCES REGARDING CYBERSECURITY OF DE-*
16 *VICES.*—Not later than 180 days after the date of enactment
17 of this Act, and not less than annually thereafter, the Sec-
18 retary shall update public information provided by the
19 Food and Drug Administration, including on the website
20 of the Food and Drug Administration, with information re-
21 garding improving cybersecurity of devices. Such informa-
22 tion shall include information on identifying and address-
23 ing cyber vulnerabilities for health care providers, health
24 systems, and device manufacturers, and how such entities
25 may access support through the Cybersecurity and Infra-
26 structure Security Agency and other Federal entities, in-

cluding the Department of Health and Human Services, to improve cybersecurity of devices.

(c) *GAO REPORT.*—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall publish a report identifying challenges in cybersecurity for devices, including legacy devices that may not support certain software security updates. Through such report, the Comptroller General shall examine—

(1) challenges for device manufacturers, health care providers, health systems, and patients in accessing Federal support to address vulnerabilities across Federal agencies;

(2) how Federal agencies can strengthen coordination to better support cybersecurity for devices; and

(3) statutory limitations and opportunities for improving cybersecurity for devices.

(d) *DEFINITION.*—In this section, the term “device” has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

SEC. 917. WOMEN’S HEALTH RESEARCH ROADMAP.

Not later than 2 years after the date of enactment of this Act, the Office of Women’s Health of the Food and Drug Administration, established under section 1011 of the Fed-

1 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 399b),*
2 *shall—*

3 *(1) review and, as appropriate, update the Wom-*
4 *en’s Health Research Roadmap issued in December*
5 *2015; and*

6 *(2) brief the Committee on Health, Education,*
7 *Labor, and Pensions of the Senate and the Committee*
8 *on Energy and Commerce of the House of Representa-*
9 *tives on the review and, as appropriate, any resulting*
10 *update.*

11 **SEC. 918. GAO REPORT ON DEATHS DUE TO THE COST OF**
12 **DRUGS IN THE UNITED STATES.**

13 *Not later than 1 year after the date of enactment of*
14 *this Act, the Comptroller General of the United States shall*
15 *publish a study on the number of individuals in the United*
16 *States who die each year because they cannot afford to pur-*
17 *chase the medicine prescribed by their health care providers.*

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117TH CONGRESS
2D Session
S. 4348

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

JULY 13, 2022

Reported with an amendment