

117TH CONGRESS
2D SESSION

H. R. 7830

To amend the Federal Food, Drug, and Cosmetic Act with respect to improving the infant formula supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 2022

Ms. STEFANIK (for herself, Mrs. RODGERS of Washington, Mrs. HINSON, and Mrs. BICE of Oklahoma) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to improving the infant formula supply chain, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Babies Need More
5 Formula Now Act of 2022”.

6 **SEC. 2. DEFINITION.**

7 In this Act, the term “infant formula” has the mean-
8 ing given to such term in section 201 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 321).

1 **SEC. 3. IMPORTATION OF INFANT FORMULA.**

2 (a) WAIVER OF LABELING REQUIREMENTS FOR IM-
3 PORTS.—Section 412 of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 350a) is amended by adding at the
5 end the following:

6 “(j) WAIVER OF LABELING REQUIREMENTS FOR IM-
7 PORTS.—

8 “(1) IN GENERAL.—The Secretary may waive
9 any labeling requirement under this Act applicable
10 to—

11 “(A) the importation of infant formula
12 from any country that is determined by the
13 Secretary to be implementing and enforcing re-
14 quirements for infant formula that provide a
15 similar assurance of safety as the regulatory re-
16 quirements of this Act; or

17 “(B) the distribution and sale of such im-
18 ported infant formula.

19 “(2) RULE OF CONSTRUCTION.—Nothing in
20 paragraph (1) shall be construed to limit the author-
21 ity of the Secretary to require a recall of, or other-
22 wise impose restrictions and requirements under this
23 Act with respect to, infant formula that is subject to
24 a waiver under paragraph (1).”.

25 (b) HARMONIZATION.—The Secretary of Health and
26 Human Services shall, when appropriate, enter into ar-

1 rangements with other nations for the purpose of harmo-
2 nizing the regulatory requirements of the United States
3 for infant formula, including with respect to inspections,
4 nutritional requirements, and common international label-
5 ing, with the corresponding regulatory requirements of
6 such other nations.

7 (c) SUPPORT FOR THE OFFICE OF THE UNITED
8 STATES TRADE REPRESENTATIVE.—Section 803(c)(2) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 383(c)(2)) is amended by striking “foods” and inserting
11 “foods (including infant formula)”.

12 (d) STUDY.—The Secretary of Health and Human
13 Services shall enter into an arrangement with the National
14 Academy of Medicine (or, if the National Academy de-
15 clines to enter into such arrangement, another appropriate
16 entity) under which the National Academy (or other ap-
17 propriate entity) agrees to—

18 (1) conduct a study comparing infant formula
19 in the United States and infant formula in the Eu-
20 ropean Union, including with respect to nutritional
21 content and applicable labeling and other regulatory
22 requirements; and

23 (2) not later than 1 year after the date of en-
24 actment of this Act, complete such study and submit
25 a report on the results of such study to the Com-

1 mittee on Energy and Commerce of the House of
2 Representatives and the Committee on Health, Edu-
3 cation, Labor, and Pensions of the Senate.

4 **SEC. 4. TRANSPARENCY TO SUPPORT INFANT FORMULA IN-**
5 **NOVATION.**

6 (a) ANNUAL REPORT TO CONGRESS.—Section 412 of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 350a), as amended by section 3(a) of this Act, is further
9 amended by adding at the end the following:

10 “(k) ANNUAL REPORT TO CONGRESS.—Not later
11 than March 30 of each year, the Secretary shall submit
12 a report to the Congress containing, with respect to the
13 preceding calendar year, the following information:

14 “(1) The number of submissions received by the
15 Secretary under subsection (d).

16 “(2) For each such submission—

17 “(A) the amount of time taken by the Sec-
18 retary to respond;

19 “(B) the number of times the Secretary re-
20 quested additional information from the person
21 making such submission; and

22 “(C) whether such submission included any
23 new ingredients that were not included in any
24 infant formula already on the market.

1 “(3) The number of inspections conducted by
2 the Food and Drug Administration or any agent
3 thereof to evaluate compliance with subsection
4 (b)(2).

5 “(4) The time between any inspection referred
6 to in paragraph (3) and any necessary reinspection
7 to evaluate compliance with subsection (b)(2).”.

8 (b) MARKETING SUBMISSIONS.—Section 412 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a),
10 as amended by subsection (a), is further amended by add-
11 ing at the end the following:

12 “(1) MARKETING SUBMISSIONS.—

13 “(1) IN GENERAL.—Subject to paragraph (2),
14 the Secretary shall respond to a submission under
15 subsection (d) for infant formula not later than 90
16 days after receiving such notification.

17 “(2) EXPEDITED RESPONSE.—The Secretary
18 shall respond to a submission under subsection (d)
19 for infant formula not later than 75 days after re-
20 ceiving such notification if it—

21 “(A) is submitted by a manufacturer that
22 is not already marketing infant formula in the
23 United States; or

24 “(B) is for infant formula containing one
25 or more ingredients that are not contained in

1 infant formula that is already being marketed
2 in the United States.

“(3) NOTIFICATION TO CONGRESS.—Whenever the Secretary fails to respond to a submission under subsection (d) by the deadline applicable under paragraph (1) or (2), the Secretary shall give notice of such failure to the Congress, including an explanation of the reasons for failing to meet the deadline.”.

(c) TECHNICAL CORRECTION.—Section 412(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(B)) is amended by striking “subsection (c)(1)” and inserting “subsection (d)(1)”.

14 SEC. 5. REDUCING BARRIERS TO INFANT FORMULA COM-
15 PETITION.

16 Not later than 180 days after the date of enactment
17 of this Act, the Secretary of Health and Human Services,
18 acting through the Commissioner of Food and Drugs,
19 shall issue guidance on which types of changes, if any, in
20 the ingredients of infant formula may not require a new
21 growth study to meet the requirements of section 412 of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 350a).

1 **SEC. 6. COORDINATION OF EFFORTS TO MITIGATE SHORT-**
2 **AGES OF INFANT FORMULA.**

3 The Secretary of Health and Human Services, acting
4 through the Commissioner of Food and Drugs, shall re-
5 quire appropriate staff of the Office of Nutrition and Food
6 Labeling, and the Office of Compliance, of the Center for
7 Food Safety and Applied Nutrition, to meet at least bi-
8 weekly to discuss, with respect to infant formula, pending
9 inspections, the findings of pending and concluded inspec-
10 tions, and any need for additional inspections.

11 **SEC. 7. IMPORTATION FOR PERSONAL USE.**

12 (a) IN GENERAL.—During the period of 90 days fol-
13 lowing the date of enactment of this Act, a person may,
14 without prior notice to the Food and Drug Administration,
15 import up to a three-month supply of infant formula for
16 personal use from Canada, the European Union, or any
17 country that is determined by the Secretary of Health and
18 Human Services, acting through the Commissioner of
19 Food and Drugs, to have safety standards for infant for-
20 mula similar to such standards applicable under the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
22 seq.).

23 (b) LIMITATIONS.—Infant formula may be imported
24 pursuant to subsection (a) only if the infant formula—

25 (1) is exclusively for personal use and will not
26 be commercialized or promoted; and

1 (2) does not present an unreasonable risk to
2 human health.

3 (c) REPORTING OF ADVERSE EVENTS.—If a health
4 care provider becomes aware of any adverse event which
5 the health care provider reasonably suspects to be associ-
6 ated with infant formula imported pursuant to subsection
7 (a), the health care provider shall report such adverse
8 event to the Food and Drug Administration.

9 (d) PUBLIC NOTICE.—The Secretary of Health and
10 Human Services, acting through the Commissioner of
11 Food and Drugs, shall post on the public website of the
12 Food and Drug Administration notice that—

13 (1) infant formula imported pursuant to sub-
14 section (a) may not have been manufactured in a fa-
15 cility that has been inspected by the Food and Drug
16 Administration;

17 (2) the labeling of such infant formula may not
18 meet the standards and other requirements applica-
19 ble with respect to infant formula under the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
21 seq.); and

22 (3) the nutritional content of the infant formula
23 may vary from that of infant formula meeting such
24 standards and other requirements.

1 (e) SENSE OF CONGRESS.—It is the sense of Con-
2 gress that persons considering the personal importation of
3 infant formula should consult with their pediatrician about
4 such importation.

5 **SEC. 8. CONSIDERATION OF SUPPLY EFFECTS PRIOR TO**
6 **RECOMMENDING OR REQUIRING A RECALL.**

7 (a) IN GENERAL.—Section 412(f) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 350a(f)(2)) is
9 amended by adding at the end the following:

10 “(4) Before recommending or requiring any recall of
11 infant formula due exclusively to labeling deficiencies, the
12 Secretary shall ensure that the supply of infant formula
13 in the United States will not be negatively affected by such
14 recall.”.

15 (b) REGULATIONS.—Not later than 3 months after
16 the date of enactment of this Act, the Secretary of Health
17 and Human Services, acting through the Commissioner of
18 Food and Drugs, shall issue or update such regulations
19 as may be necessary to implement paragraph (4) of section
20 412(f) of the Federal Food, Drug, and Cosmetic Act, as
21 added by subsection (a).

22 **SEC. 9. CONGRESSIONAL NOTIFICATION.**

23 (a) IN GENERAL.—Not later than 24 hours after the
24 initiation of a recall of infant formula, the Secretary of
25 Health and Human Services, acting through the Commis-

1 sioner of Food and Drugs, shall submit to the Congress
2 a notification of such recall.

3 (b) CONTENTS.—A notification under subsection (a)
4 shall include the following:

5 (1) If the recall is required by the Food and
6 Drug Administration, a summary of the determina-
7 tion of a case of adulterated or misbranded infant
8 formula that presents a risk to human health.

9 (2) If the recall is voluntarily initiated by the
10 manufacturer, a summary of the information pro-
11 vided to the Food and Drug Administration by the
12 manufacturer regarding infant formula that has left
13 the control of the manufacturer that may be adulter-
14 ated or misbranded.

15 (3) Specification of when the Food and Drug
16 Administration was first made aware of the instance
17 or circumstances surrounding the recall.

18 (4) An initial estimate of the disruption in do-
19 mestic production that may result from the recall.

20 **SEC. 10. REPORT TO CONGRESS.**

21 (a) IN GENERAL.—Not later than 14 days after the
22 initiation of a recall of infant formula, the Secretary of
23 Health and Human Services, acting through the Commis-
24 sioner of Food and Drugs, shall submit a report to the
25 Congress regarding such recall.

1 (b) CONTENTS.—A report under subsection (a) shall
2 include the following:

3 (1) A plan (including an estimated timeline) of
4 actions the Food and Drug Administration and the
5 manufacturer will take—

6 (A) to identify and address any cause of
7 adulteration or misbranding; and

8 (B) to restore operation of the impacted
9 facilities to meet production levels in place prior
10 to the recall.

11 (2) The current domestic supply of infant for-
12 mula, including—

13 (A) a breakdown of the specific types of
14 formula involved; and

15 (B) an estimate of how long current sup-
16 plies will last.

17 (3) In the case that a recall and subsequent ac-
18 tions to respond to the recall impact over 10 percent
19 of the domestic production of infant formula, a plan
20 to backfill supplies if the current domestic supply of
21 infant formula has or is expected to fall below the
22 level demanded during the disruption in domestic
23 production, which plan shall include—

1 (A) actions to work with the impacted
2 manufacturer or other manufacturers to in-
3 crease production; and

4 (B) specification of—

5 (i) any additional authorities needed
6 regarding production or importation to fill
7 a supply gap; and

8 (ii) any supplemental funding nec-
9 essary to address the shortage.

10 **SEC. 11. COORDINATION WITH MANUFACTURER ON RE-**
11 **STORING PRODUCTION.**

12 (a) IN GENERAL.—Upon completing an inspection of
13 an infant formula manufacturing facility impacted by a
14 recall, the Secretary of Health and Human Services, act-
15 ing through the Commissioner of Food and Drugs, shall
16 provide the manufacturer involved a list of any actions
17 necessary—

18 (1) to address deficiencies contributing to the
19 potential adulteration or misbranding of product at
20 the facility; and

21 (2) to safely restart production at the facility.

22 (b) RESPONSE TO MANUFACTURER.—Not later than
23 7 days after receiving a written communication from a
24 manufacturer of infant formula regarding safely restoring
25 production following a recall of such product, the Sec-

1 retary of Health and Human Services, acting through the
2 Commissioner of Food and Drugs, shall provide a sub-
3 stantive response to such communication, including any
4 necessary next steps.

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