The Honorable Laura Kelly
Governor, State of Kansas
State Capitol, 300 SW 10th Ave., Ste. 241S
Topeka, KS 66612-1590

The Honorable Tim Walz
Governor, State of Minnesota
130 State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

The Honorable Phil Scott
Governor, State of Vermont
109 State Street, Pavilion
Montpelier, VT 05609

The Honorable Tony Evers
Governor, State of Wisconsin
115 East State Capitol
Madison, WI 53707

March 19, 2021

Re: FDA-2006-P-0282

Dear Governors Kelly, Walz, Scott, and Evers:

This letter responds to the citizen petition dated August 3, 2006 (Petition), that was submitted by the governors of Kansas, Minnesota, Vermont, and Wisconsin at that time (Petitioners) to the Food and Drug Administration (FDA or the Agency).

The Petitioners "request that FDA promptly issue guidance documents outlining the specific approval requirements for forms of insulin and [human growth hormone (HGH)] that are therapeutically equivalent to the brand products currently approved by FDA" (Petition at 3). Petitioners "also request that the FDA commit to working with drug companies developing such products and to expediting the application process so that these products may be approved and made available to patients as quickly as possible" (Petition at 3).

The Petitioners assert that FDA "has yet to permit an applicant to seek approval of therapeutically equivalent versions of insulin under Section 505(b)(2) and has not described the standard by which any such application would be approved or disapproved" and that FDA has only recently approved a new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)) for HGH (Petition at 2). The Petitioners maintain that issuance of guidance will facilitate the availability of more

affordable, therapeutically equivalent versions of insulin and HGH, which would help States reduce the burden of excessive pharmaceutical costs (Petition at 1).

We have carefully considered the Petition and comments submitted to the public docket.[1] FDA shares your concern that patients and communities are struggling to afford the cost of life-saving products such as insulin and has been working hard to facilitate the submission of marketing applications for insulin, including "follow-on"[2] insulin products that may be approved under section 351(k) of the Public Health Service Act (PHS Act), and HGH products and thereby encourage competition. The March 23, 2020, transition of biological products previously regulated under the FD&C Act to regulation under the PHS Act will enable the approval of insulin and HGH products that are biosimilar to, or interchangeable with, a transitioned insulin or HGH product. Biosimilar and interchangeable insulin and HGH products can help increase access and, ultimately can provide more affordable treatment options for patients. For the reasons further described below, the Petition is granted in part and denied in part.

I. BACKGROUND

A. Insulin

Insulin is a hormone produced by the pancreas that lowers the concentration of glucose in the blood by inhibiting glucose production in the liver and by stimulating the uptake and metabolism of glucose by muscle and adipose tissue.[3] Insulin products are approved to improve glycemic control in specified populations of patients with diabetes mellitus.

Animal-sourced insulins (extracted from bovine or porcine pancreas) were available for the treatment of diabetes mellitus beginning in the 1920s, but are no longer approved in the United States. In 1982, FDA approved the first insulin product manufactured using recombinant deoxyribonucleic acid (rDNA) technology. That product has the same amino acid sequence as native human insulin, which is composed of 51 amino acids. FDA also has approved insulin analog products, which are forms of insulin that have been modified in structure (i.e., there are differences from human insulin in the amino acid sequence) and are faster-acting or longer-acting than recombinant human insulin. Insulin mix products are a mixture of various recombinant human insulins or insulin analogs. All currently approved human insulin products, insulin analog products and insulin mix products (collectively described in this response as "insulin products"), are manufactured using rDNA technology and were originally approved in NDAs under the FD&C Act.

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[1] The states of Mississippi, Montana, Nevada, Virginia, Washington and West Virginia, along with Consumer Union, submitted comments in support of the Petition.

[2] We sometimes use the informal term "follow on" product to describe a product that has been approved through an abbreviated approval pathway.

[3] See Davis SN, Granner DK. Insulin, Oral Hypoglycemic Agents, and the Pharmacology of the Endocrine Pancreas. In *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 10th ed. New York: McGraw-Hill, 2001, at 1689.

Before the March 23, 2020, transition of biological products previously regulated under the FD&C Act to regulation under the PHS Act,[4] FDA had approved three "follow-on" insulin products in NDAs submitted pursuant to section 505(b)(2) of the FD&C Act:[5] Basaglar (insulin glargine) injection, Admelog (insulin lispro) injection, and Myxredlin (insulin human) in 0.9% sodium chloride injection.[6] However, no prescription insulin products were rated by FDA as therapeutically equivalent.[7]

B. Human Growth Hormone

HGH is produced by the pituitary gland and can stimulate tissue growth, linear growth (height), and protein, carbohydrate, lipid, and mineral metabolism.[8] HGH manufactured using rDNA technology (somatropin) has an identical amino acid sequence to HGH of pituitary origin and is composed of 191 amino acids. FDA has approved NDAs for 10 somatropin product lines, including an original 505(b)(2) application (Omnitrope) and 505(b)(2) supplements for approval of additional indications for Norditropin and Zomacton. Some somatropin products have approved indications in both the adult and pediatric populations. For example, somatropin products have been approved in the pediatric population for uses that may include treatment of growth failure due to growth hormone deficiency, Turner syndrome, Noonan syndrome, Prader-Willi syndrome, short stature homeobox-containing gene (SHOX) deficiency, chronic renal insufficiency, idiopathic short stature and children small for gestational age. All currently

[4] See section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) as amended by the Further Consolidated Appropriations Act, 2020.

[5] A 505(b)(2) application contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (e.g., published literature or FDA's finding of safety and/or effectiveness for a listed drug). The 505(b)(2) approval pathway has been used for follow-on products that have been demonstrated to be sufficiently similar to a listed drug to scientifically justify reliance on FDA's finding of safety and/or effectiveness for the listed drug to support approval. Any aspects of the proposed drug product that differ from the listed drug must be supported by adequate data and information in the 505(b)(2) application to demonstrate that the proposed drug product meets the statutory approval standard for safety and effectiveness.

[6] A fourth follow-on insulin product, Semglee (insulin glargine) injection, was approved on June 11, 2020, and pursuant to section 7002(e)(4)(B) of the BPCI Act, which was added by section 607 of the Further Consolidated Appropriations Act, 2020 (FCA Act), the approved NDA was deemed to be a license for the biological product under section 351(a) of the Public Health Service Act upon approval.

[7] See section I.C of this response; see also FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), March 20, 2020 ed., at 266-268. FDA does not make therapeutic equivalence determinations for products with over-the-counter status that are the subject of an approved application under section 505 of the FD&C Act.

[8] Melmed S. Pathogenesis and Diagnosis of Growth Hormone Deficiency in Adults. N Engl J Med. 2019; 380(26):2551-2562.

approved somatropin products were originally approved in NDAs under the FD&C Act, and none of the products had been rated by FDA as therapeutically equivalent.[9,10]

C. Therapeutic Equivalence Evaluations for Products Approved Under Section 505 of the FD&C Act

Therapeutically equivalent products are defined as "approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling."[11] In the Orange Book, FDA further explains that it classifies as therapeutically equivalent those products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents[12] in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent[13] in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable *in vitro* standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.[14]

Section 505(j) of the FD&C Act, together with its implementing regulations, generally require that an abbreviated new drug application (ANDA) demonstrate that the proposed generic drug product and the applicable reference listed drug (RLD) are the same with respect to their active ingredient(s), dosage form, route of administration, strength, conditions of use, and labeling (with certain exceptions).[15] An ANDA must also include sufficient information (1) to

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[9] See the Orange Book, March 20, 2020 ed., at 430-431.

[10] While Omnitrope was the first HGH product approved through the 505(b)(2) pathway, it had not been determined therapeutically equivalent to any other HGH product. Rather, FDA assigned Omnitrope a "BX" rating, which means the data that had been reviewed by the Agency were insufficient to determine therapeutic equivalence and the drug products are presumed to be therapeutically inequivalent until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence (see the Orange Book Preface, 40th ed., at xx).

[11] § 314.3 (21 CFR 314.3) (defining therapeutic equivalents).

[12] Pharmaceutical equivalents are "drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient, *i.e.*, the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates." § 314.3.

[13] Bioequivalence is "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." § 314.3.

[14] See Orange Book Preface, 40th ed. at vii.

[15] See section 505(j)(2)(A) and 505(j)(4) of the FD&C Act and 21 CFR 314.94 and 314.127.

demonstrate that the proposed product is bioequivalent to the RLD[16] and (2) to ensure the product's identity, strength, quality, and purity.[17] A drug product approved in an ANDA is presumed to be therapeutically equivalent to its RLD. However, a drug product approved through the 505(b)(2) pathway may differ in certain respects from a previously approved product and a demonstration of therapeutic equivalence is not required for a determination that the proposed drug product meets the statutory approval standard for safety and substantial evidence of effectiveness.[18] In many cases, the differences between a product approved in a 505(b)(2) application and a listed drug foreclose a finding that the products are therapeutically equivalent, for example, if they are not pharmaceutically equivalent. In other cases, however, a drug product approved pursuant to a 505(b)(2) application and a listed drug may satisfy the therapeutic equivalence criteria.

FDA publishes therapeutic equivalence (TE) codes reflecting whether the Agency has evaluated a particular approved product as therapeutically equivalent to another pharmaceutically equivalent product(s) in the Orange Book. The Agency only makes therapeutic equivalence determinations for drug products approved under section 505 of the FD&C Act; FDA does not make therapeutic equivalence determinations for biological products regulated under the PHS Act and listed in the Purple Book.

D. Statutory Transition of Certain Protein Products to Regulation Under the PHS Act

Although the majority of therapeutic biological products have been licensed under section 351 of PHS Act, some protein products, including insulin and HGH, historically, and at the time of this request, were approved under section 505 of the FD&C Act. On March 23, 2010, the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Public Law 111-148). The BPCI Act amended the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar[19] to, or interchangeable[20] with, an FDA-licensed reference product.[21] The BPCI Act, as amended by the Further Consolidated Appropriations Act, 2020 (FCA Act), also clarified the statutory authority under which certain protein products will be regulated by amending the

[16] See section 505(j)(2)(A)(iv) and 505(j)(4)(F) of the FD&C Act and 21 CFR 320.21(b).

[17] See section 505(j)(2)(A)(vi) and 505(j)(4)(A) of the FD&C Act and 21 CFR 314.94(a)(9) and 314.127(a)(1).

[18] See section 505(b), 505(c), and 505(d) of the FD&C Act.

[19] Biosimilar means that the proposed product has been shown to be "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" (section 351(i)(2) of the PHS Act).

[20] Interchangeable means that the proposed product has been shown to meet the standards in section 351(k)(4) of the PHS Act and may be substituted for the reference product without the intervention of the prescribing health care provider (section 351(i)(3) of the PHS Act). See section II.B of this response.

[21] See section 351(i)(4) of the PHS Act.

definition of a "biological product" in section 351(i) of the PHS Act to include a "protein"[22] and describing procedures for submission of a marketing application for certain biological products. The BPCI Act requires that a marketing application for a "biological product" (that previously could have been submitted under section 505 of the FD&C Act) must be submitted under section 351 of the PHS Act; this requirement was subject to certain exceptions during a 10-year transition period that ended on March 23, 2020.[23]

The BPCI Act required that on March 23, 2020 (i.e., the transition date), former approved NDAs for biological products, which included NDAs for insulin and HGH products,[24] under section 505 of the FD&C Act were deemed to be licenses for the biological products (i.e., approved biologics license applications (BLAs)) under section 351 of the PHS Act.[25] After March 23, 2020, all manufacturers seeking approval of a biological product that previously could have been submitted under section 505 of the FD&C Act (such as insulin or HGH) must submit a marketing application under either section 351(a) or 351(k) of the PHS Act.[26]

II. DISCUSSION

A. Petitioners' request for issuance of guidance describing recommendations for establishing the therapeutic equivalence of insulin or HGH products regulated under the FD&C Act is superseded by the recent transition of these products to regulation under the PHS Act

The Petition requests that FDA issue product-specific guidance documents for the approval of therapeutically equivalent versions of insulin and HGH drug products (Petition at 3). We deny this request for the reasons explained below.

In support of this request, the Petition asserts there are no legal obstacles to the approval of therapeutically equivalent versions of insulin and HGH because both products are regulated under the FD&C Act unlike most other biological products, which are regulated under the PHS Act (Petition at 7). Additionally, the Petition maintains that there are no scientific reasons for delaying issuance of product-specific guidances for insulin and HGH because the Petition

[22] See 21 CFR 600.3(h) as amended by 85 FR 10057 (February 21, 2020) to incorporate changes made to the definition of "biological product" by the BPCI Act and the FCA Act, and to provide FDA's interpretation of the statutory term "protein."

[23] See section 7002(e)(1)-(3) and (e)(5) of the BPCI Act.

[24] FDA determined that insulin and HGH fall within the Agency's interpretation of the term "protein" in the statutory definition of "biological product" because they are alpha amino acid polymers with a specific, defined sequence that is greater than 40 amino acids in size.

[25] See section 7002(e)(4)(A) of the BPCI Act; see also section 7002(e)(4)(B) of the BPCI Act. See also Q7 of FDA's guidance on "The 'Deemed to be a License' Provision of the BPCI Act Questions and Answers," where we explain that FDA interprets section 7002(e)(4) of the BPCI Act (i.e., the transition provision), along with the applicable provisions of the FD&C Act and the PHS Act, to mean that an approved NDA, including an application submitted through the pathway described by section 505(b)(2) of the FD&C Act, will be deemed to be a 351(a) BLA on the transition date.

[26] See section 7002(e)(1) of the BPCI Act.

contends both products are well-understood products for which therapeutically equivalent versions can be developed (Petition at 7). The Petition states that its request is supported by FDA public statements that suggest FDA has drafted product-specific guidances concerning therapeutic equivalence and is also supported by the approval of Omnitrope (somatropin) (Petition at 7-8).

FDA has been actively working for many years to facilitate efforts by manufacturers to develop and obtain approval of marketing applications for insulin and HGH products, and thereby encourage competition. Although FDA initially indicated its intention to issue guidance describing recommendations for the development of follow-on insulin and somatropin products through the 505(b)(2) pathway, the Agency explained that "as our knowledge of this issue expanded, we reconsidered our focus and determined it would be more appropriate to initially promulgate guidance that is more broadly applicable to follow-on protein products in a comprehensive manner through issuance of a series of guidance documents."[27]

The Agency has emphasized that the absence of product-specific guidance does not limit FDA's ability to work with prospective applicants of proposed insulin and HGH products on a product-specific basis.[28] Prior to the statutory transition of insulin and HGH products to regulation under the PHS Act, FDA approved follow-on insulin and HGH products through the 505(b)(2) pathway.[29]

As of March 23, 2020, insulin and HGH products are no longer regulated under the FD&C Act but instead are regulated under the PHS Act. Accordingly, FDA would no longer evaluate whether an insulin or HGH product is therapeutically equivalent to another insulin or HGH product, because the designation is only applicable to products approved under section 505 of the FD&C Act. For this reason, we deny the Petition's request for issuance of guidance describing recommendations for establishing the therapeutic equivalence of insulin or HGH products regulated under the FD&C Act.

The transition of approved applications for biological products under the FD&C Act to the PHS Act on March 23, 2020, enables prospective applicants to submit applications for approval of insulin and HGH products that are biosimilar to, or interchangeable with, these transitioned

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[27] Statement of Janet Woodcock, M.D., Deputy Commissioner, Chief Medical Officer, Food and Drug Administration, Before the Committee on Oversight and Government Reform, United States House of Representatives, "Follow-on Protein Products", March 26, 2007, at p. 16.

[28] Petitioners assert that failure to issue product-specific guidance documents for the development of insulin and HGH that are therapeutically equivalent to approved products violates the Administrative Procedure Act (APA) (Petition 8-9). Petitioners assert that "FDA made this decision without offering any justification, and Petitioners are not aware of any justification that could support the Agency's decision." (Petition at 8). The APA does not require FDA to justify a decision not to issue a particular product-specific guidance document.

[29] While FDA had approved follow-on protein products, such as insulin and HGH, under the FD&C Act, the Petition mischaracterizes the term "follow-on protein products" as the "Agency's name for therapeutically equivalent biologics . . . ." (Petition at 7). Approval of an application submitted pursuant to section 505(b)(2) of the FD&C Act does not mean the product has demonstrated therapeutic equivalence, and the term "follow-on protein products" is not the same as "therapeutically equivalent biologics."

products. In anticipation of the statutory transition, FDA has worked to implement the abbreviate pathway established in the BPCI Act, including working with prospective applicants seeking to develop proposed biosimilar and interchangeable products for submission in BLAs submitted under section 351(k) of the PHS Act.

B. FDA remains committed to continuing to work with manufacturers interested in developing insulin and HGH products intended to expand patient options

The Petition requests that FDA commit to working with drug companies developing insulin and HGH products that are therapeutically equivalent to approved products currently approved by FDA and to expedite the application process for such products (Petition at 3). For the reasons explained above, FDA does not evaluate whether an insulin or HGH product is therapeutically equivalent to another insulin or HGH product. Nonetheless, we grant this part of the Petition's request to the extent that FDA remains committed to continuing to work with manufacturers interested in submitting marketing applications for proposed biosimilar and interchangeable insulin and HGH products.

An applicant seeking licensure as *interchangeable* must provide sufficient information to demonstrate that the proposed product is biosimilar to the reference product,[30] that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once to an individual, such as insulin or HGH, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act).[31] Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider.[32] The transition of approved former NDAs for proteins such as insulin and HGH to deemed 351(a) BLAs pursuant to the transition provision of the BPCI Act enables potential applicants to seek licensure of products that are biosimilar to, or interchangeable with, these transitioned products.

To facilitate the timely development of biosimilar and interchangeable products, generally, the Agency has established a biosimilar action plan (BAP). As part of this plan, the Agency is taking steps to improve efficiency in biosimilar development and in the FDA's review and

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[30] *Biosimilarity* means that that the proposed product has been shown to be "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" (see section 351(i)(2) of the PHS Act).

[31] We note, under the circumstances described in FDA's draft guidance on *Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products*, which is discussed later in this response, such demonstration may made through a comprehensive and robust comparative analytical assessment demonstrating that the proposed interchangeable insulin product is "highly similar" to the reference product without data from comparative clinical immunogenicity studies.

[32] Section 351(i)(3) of the PHS Act.

licensure of biosimilars; to educate clinicians, payers, and patients about biosimilar products and the rigorous evaluations they must go through; and to modernize regulatory policies to accommodate new scientific tools that can better enable comparison between biosimilar and reference products that may reduce the need for clinical studies.[33]

As part of its effort to facilitate the development of biosimilar and interchangeable products, FDA has issued numerous guidances for industry[34] including: *Considerations in Demonstrating Interchangeability With a Reference Product* (May 2019); *Questions and Answers on Biosimilar Development and the BPCI Act* (December 2018); *Labeling for Biosimilar Products* (July 2018); *Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product* (December 2016); and *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (April 2015). In addition, specific to the development of therapeutic proteins, which include insulin and HGH, FDA issued a draft guidance for industry on the *Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations* (May 2019).[35] These guidances, along with other biosimilar guidances FDA has previously issued,[36] are intended to assist companies developing biosimilar and interchangeable products, including therapeutic proteins such as insulin and HGH.

In addition, with respect to insulin, in November 2019, FDA issued a draft guidance on *Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products* (Insulin Draft Guidance), which describes FDA's updated thinking regarding circumstances in which a comparative clinical immunogenicity study generally would be unnecessary to support licensure of a proposed biosimilar and interchangeable recombinant human insulin, recombinant human insulin mix product, or recombinant insulin analog product that is intended for the treatment of patients with Type 1 or Type 2 diabetes mellitus and for which a robust and comprehensive comparative analytical assessment demonstrates that the proposed insulin product is "highly similar" to its reference product. The draft guidance explains that, in such circumstances, comparative clinical immunogenicity data will not typically be necessary to evaluate the potential risk and clinical impact of immunogenicity of proposed biosimilar and interchangeable insulin products.[37] In addition, the draft guidance describes data expectations for proposed biosimilar and interchangeable insulin products.[38] FDA expects that this approach will help

[33] For additional information on FDA's Biosimilar Action Plan, see "BIOSIMILARS ACTION PLAN: Balancing Innovation and Competition," July 2018, available at: https://www.fda.gov/media/114574/download.

[34] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[35] When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check on the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[36] FDA provides ongoing guidance about demonstrating biosimilarity and interchangeability through publishing guidance documents, available at:https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs (search Biosimilars).

[37] Insulin Draft Guidance at pp. 3-5.

[38] Id., at pp. 5-7.

increase the efficiency of development for biosimilar and interchangeable insulin products, while still ensuring that FDA's robust standards for approval are met.[39]

The Agency recognizes that increases in the prices of insulin products raise serious concerns with respect to the ability of many individuals to access the insulin they need to survive. FDA held a public hearing in 2019 to receive input from stakeholders as the Agency prepared for the submission and review of applications for biosimilar and interchangeable insulin products.[40] The hearing included discussion on access to affordable insulin products and issues related to the development and approval of biosimilar and interchangeable insulin products.[41]

FDA remains committed to working with companies to advance the development of biosimilar and interchangeable insulin and HGH products that are more affordable and accessible.

III. CONCLUSION

For the reasons described above, the Petition is denied in part with respect to issuing product-specific guidance for the development of insulin and HGH that are therapeutically equivalent to approved brand products. In addition, although FDA does not evaluate whether an insulin or HGH product is therapeutically equivalent to another insulin or HGH product, the Petition is granted in part, in that FDA remains committed to fostering the efficient development of biosimilar and interchangeable insulin and HGH products to expand access and improve the lives of patients and their families.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300121270, cn=Douglas C. Throckmorton -S
Date: 2021.03.19 14:33:16 -04'00'

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research

[39] When final, this guidance will represent FDA's current thinking on this topic. FDA is currently reviewing comments submitted to the docket for this draft guidance and intends to publish revised draft or final guidance as soon as practicable.

[40] See 64 FR 12966 (April 3, 2019).

[41] See the meeting transcript of "The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products", May 13, 2019, available at: https://www.fda.gov/media/126733/download.