4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-5743]

Importation of Certain Food and Drug Administration-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: This document corrects the Notice of Availability from the Food and Drug Administration (FDA, Agency, or we) announcing the availability of a draft guidance for industry entitled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act," which published in the *Federal Register* on Monday, December 23, 2019. This draft guidance describes procedures to obtain a National Drug Code (NDC) for an FDA-approved prescription drug that is imported into the United States in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. This draft guidance is intended to address certain challenges in the private market faced by manufacturers seeking to sell their drugs at lower costs. The Notice was published with two omissions. This document corrects those omissions by republishing the Notice in its entirety to include the omitted language.

DATES: Submit either electronic or written comments on the draft guidance by February 21, 2020, to ensure that the Agency considers your comment on this draft guidance before it

begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-5743 for "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act."[1] Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information

[1] In the *Federal Register* of December 23, 2019 (84 FR 70557), FDA issued a Notice of Availability for this guidance, the subject of this correction notice.

about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7605, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act," which, when finalized, will represent the Agency's current thinking on the importation of multi-market approved (MMA) products. This draft guidance describes procedures to obtain an NDC for an FDA-approved prescription drug that is imported into the United States in compliance with section 801 of the FD&C Act (21 U.S.C. 381), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. In recent years, FDA has become aware that some drug manufacturers may be interested in offering certain of their drugs at lower costs and that obtaining additional NDCs for these drugs may help them to address certain challenges in the private market. This guidance is not intended to address the applicability of the Medicaid drug rebate program for manufacturers, which may be addressed in further guidance from other components of HHS. This guidance is intended to outline a potential pathway by which manufacturers could obtain an additional NDC for an FDA-approved drug that was originally intended to be marketed in a foreign country. This guidance specifically addresses the importation of FDA-approved drugs that were also authorized for sale in a foreign country in which the drugs were originally intended to be marketed ("MMA product"). This guidance describes: (1) the process for submitting a supplement to an approved FDA application for an MMA product; (2) the recommended labeling for an MMA product; (3) the process for registration and listing and for obtaining an NDC for the MMA product; (4) the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee-1) as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54); (5) recommendations related to procedures for

importation of the MMA product; and (6) other FDA requirements applicable to MMA products.

This guidance, when finalized, will help ensure manufacturers are aware of procedures to provide access to lower-cost drugs in the United States.[2] The guidance details procedures that will enable manufacturers to obtain an additional NDC for the MMA product, which could allow greater pricing flexibility for a drug or biological product. The additional NDC also will support pharmacovigilance, accurate billing and reimbursement, and facilitate clearance of the MMA products through customs. This draft guidance is not final nor is it in effect at this time.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the importation of MMA products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Issues for Consideration

As previously noted, FDA is interested in receiving comments on the draft guidance. Regarding the approach set forth in the draft guidance, in addition to any other issues addressed, FDA requests that commenters consider the following issues when submitting comments:

1. Are there additional considerations for certain types of drug products with special handling, such as sterile injectables, drugs with boxed warnings, drugs with REMS (Risk Evaluation and Mitigation Strategy), controlled substances, or drugs that do not meet the definition of "product" under the DSCSA (21 U.S.C. 360eee(13))? Are there additional considerations for combination products related to the content of the guidance (e.g.,

[2] In the *Federal Register* of December 23, 2019 (84 FR 70796), FDA issued a Notice of Proposed Rulemaking under 21 U.S.C. 384 to offer a pathway for importation of drugs from Canada without the authorization of the manufacturer.

supplement, labeling, NDC) that would warrant additional guidance for use of this approach for those products? To the extent that interested parties believe that different or additional considerations from those described in the draft guidance should apply to such an approach for combination products, we are interested in input on that, as well.

2. The draft guidance uses "MMA product" to describe FDA-approved drugs that were originally intended to be marketed in a foreign country and also authorized for sale in that foreign country. Is this new term adequate and understandable? Is there another term that would provide more clarity regarding the products discussed in the guidance?
3. The draft guidance describes how an NDC could be obtained for MMA products. What is the effect of a manufacturer using a new labeler code as opposed to a new product code to distinguish these products, such as for reimbursement?
4. The draft guidance recommends a labeling statement in the FDA-approved labeling for the MMA product, including the carton and container label, to assist pharmacists and others in accurately identifying, dispensing, and billing for these products. FDA seeks comment on the specific wording that could be included in the statement to differentiate MMA products from other drugs that are not the subject of the guidance, if finalized, and to help ensure MMA products are easily identifiable to pharmacists and not confusing to patients. FDA also seeks comment on other types of distinguishing characteristics on the carton and container label that would further enable pharmacists to identify an MMA product and distinguish it from other packages of the FDA-approved drug, without confusing patients and consistent with other applicable requirements relating to carton and container labeling. Additionally, would other possible mechanisms, such as a Dear Healthcare Provider letter, provide further clarity and reduce confusion for pharmacists

and other healthcare providers as well as patients?

5. We request comment about how much, on average, the labeling and packaging changes described in the draft guidance would cost drug manufacturers and repackagers or relabelers. Are there other ways to distinguish the appearance of an MMA product? We also request comment about alternative labeling approaches that would display the required information with equal prominence but may result in lower costs.
6. The draft guidance describes procedures for manufacturers of drug products approved under new drug applications or biologics license applications to obtain an additional NDC for an MMA product. FDA is interested as to whether manufacturers of generic drugs approved under an abbreviated new drug application confront similar pricing issues such that it would be appropriate to provide guidance on a similar approach for generic drugs. To the extent that interested parties believe that different considerations should apply to such an approach for generic drugs from those described in the draft guidance, input is requested on that as well.
7. There are complex considerations that impact biosimilar development, market entry, and uptake. We are interested in the possible impacts of MMA products that are biological products on biosimilar development, market entry, and uptake.
8. Similarly, there are complex considerations impacting generic drug market entry. We are interested in the possible impacts of MMA products on generic drug development and market entry.
9. Are there voluntary steps a manufacturer may take in addition to the requirements in the DSCSA to ensure the security of the supply chain for products imported pursuant to the guidance?

10. Are there any potential risks associated with the importation of products as described in the draft guidance that could be addressed by a rulemaking? For example, to what extent, if any, are there additional procedures that might better protect against entities seeking to introduce counterfeit drugs in the United States? If so, please be specific about the potential risk and how it could be addressed through rulemaking.
11. The draft guidance describes a pathway that manufacturers could use to offer their products to Americans at a lower price. FDA is interested in the factors that could contribute to the decision to use this pathway and whether there are reasons to use this pathway other than the ability to sell products at a lower price.

III. Paperwork Reduction Act of 1995

FDA has tentatively concluded that there are no new collections of information in this draft guidance. This draft guidance refers to previously approved collections of information found in the FD&C Act and FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). In accordance with the Paperwork Reduction Act, if FDA's tentative conclusion changes, prior to publication of any final guidance document FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

The collections of information in 21 CFR part 314 (new drug applications) have been approved under OMB control number 0910-0001; the collections of information in 21 CFR part 601 (biologics license applications) have been approved under OMB control number 0910-0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration,

including assignment of an NDC) have been approved under OMB control number 0910-0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910-0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910-0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910-0139 and 0910-0834; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910-0806.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: December 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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