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, and Combination Products Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act." This guidance describes recommended procedures to obtain a National Drug Code (NDC) for certain FDA-approved prescription drugs that are 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 these drugs could be sold at a lower cost in the U.S. market. This guidance is intended to address certain challenges in the private market faced by manufacturers seeking to sell their drugs at lower costs. This guidance finalizes the draft guidance issued on December 23, 2019.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act." 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. 240-402-7500.

- 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 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. 240-402-7500.

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

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6180, Silver Spring, MD 20993-0002, 301-796-7605; 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; or the Office of Regulatory Affairs (ORA), Office of Strategic Planning and Operational Policy at ORAPolicyStaffs@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act." This guidance represents the Agency's current thinking on the importation of certain FDA-approved drugs, including biological products, and combination products that are the subject of approved new drug applications (NDAs) or biologics license applications (BLAs) and that are also authorized for sale in a foreign country in which the products were originally intended to be marketed. These are referred to in the guidance as "multi-market approved" ("MMA") products. This guidance describes procedures to obtain an NDC for an FDA-approved 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 a number of their drugs at lower costs and that obtaining NDCs for their drugs may help them to address certain challenges in the private market. This guidance is not intended to address the applicability of programs administered by the Centers for Medicare & Medicaid Services such as the Medicaid drug rebate program for manufacturers. The Department of Health and Human Services (HHS) may issue further guidance or rulemaking as appropriate. HHS guidance, including relevant Medicaid guidance for drugs imported following the procedures in this guidance, can be found at https://www.hhs.gov/guidance/.

This guidance describes: (1) the process for submitting a supplement to an approved NDA or BLA 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 (Title II of Pub. L. 113-54); (5) recommendations related to procedures for importation of the MMA product; and (6) other requirements applicable to MMA products.

This guidance will help ensure manufacturers are aware of procedures to facilitate manufacturers' ability to provide access to lower-cost drugs in the United States. The guidance details procedures that will enable manufacturers to obtain an NDC for the MMA product, which could allow manufacturers to offer a drug, biological product, or combination product at a lower cost. The NDC for the MMA product also will support pharmacovigilance, aid in accurate billing and reimbursement, and facilitate clearance of the MMA products through FDA's admissibility review.

This guidance finalizes the draft guidance 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: Draft Guidance for Industry," issued on December 23, 2019 (84 FR 71961). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: clarifying the description of MMA products, including combination products; providing additional recommendations for the labeling of MMA products to help ensure that MMA products may be readily identified; and providing a template "Dear Healthcare Provider" letter that manufacturers may use to alert healthcare professionals of the availability of an MMA product.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and

Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act." 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. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this 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 OMB under the PRA. The collections of information in 21 CFR part 314 (NDAs) have been approved under OMB control number 0910-0001; the collections of information in 21 CFR part 601 (BLAs) 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; the collection of information pertaining to Dear Health Care Provider Letters has been approved under OMB control number 0910-0754;

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.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs; https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances; https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents; or https://www.regulations.gov.

Dated: September 23, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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