product quality attributes that affect drug dissolution and absorption, and discusses how to capture and present model assumptions and parameters. Model validation and refinement are also discussed.

In addition, the guidance discusses the major regulatory uses of PBPK modeling for biopharmaceutics applications with respect to supporting product quality. Factors regarding the development of clinically relevant dissolution specifications to aid in biopredictive dissolution method development and to support clinically relevant dissolution acceptance criteria are presented, as well as considerations for conducting virtual bioequivalence studies.

PBPK modeling for biopharmaceutics applications also can be used to establish clinically relevant drug product quality specifications other than dissolution, which can be used to ensure bioequivalence of batches within the specification limits, to the pivotal clinical/bioavailability batches, or to the reference listed drug for generic drugs. Finally, the guidance discusses the use of PBPK analyses for biopharmaceutics applications as an advanced tool for quality risk assessment and management in both the pre- and postapproval stages.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.'' 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This draft guidance refers to previously approved FDA collections of information. 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). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: September 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21652 Filed 9–30–20; 8:45 am]

BILLING CODE 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 October 1, 2020.

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.

[FR Doc. 2020–21521 Filed 9–25–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicaid Reentry Stakeholder Group

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

ACTION: Notice of Establishment of the Medicaid Reentry Stakeholder Group and Request for Nominations.

SUMMARY: The Secretary of HHS has determined that establishment of the Medicaid Reentry Stakeholder Group, as required by the Medicaid Reenty Act, is desirable to provide advice and consultation to the Secretary on innovative strategies to help individuals who are inmates of public institutions, and otherwise eligible for Medicaid, ensure continuity of coverage and seamless transitions back to the community. HHS is soliciting nominations for non-Federal members of the Stakeholder Group.

DATES: Submit nominations by email before COB on October 23, 2020.

ADDRESSES: Nominations should be sent to Jhamirah Howard at *jhamirah.howard@hhs.gov* ; Jhamirah Howard, MPH., Office of the Assistant Secretary for Planning and Evaluation, Room 424E Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jhamirah Howard (202) 690–1721, *jhamirah.howard@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Medicaid Reentry Act, Public Law 115–271, title IV, subtitle D, 132 Stat. 3965 (Oct. 24, 2018) (42 U.S.C. 1396a note) requires that the Secretary of Health and Human Services (HHS) establish the Medicaid Reentry Stakeholder Group. The Stakeholder Group is governed by provisions of Public Law 92–463 (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. The Secretary signed the charter establishing the Stakeholder Group on July 30, 2020. HHS is soliciting nominations for non-Federal members of the Stakeholder Group. Nominations should include the nominee's contact information (current mailing address, email address, and telephone number) and a current curriculum vitae or resume.

The Stakeholder Group will meet once, to develop best practices (and submit to the Secretary and Congress a report on such best practices) for States—(A) to ease the health care-related transition of an individual who is an inmate of a public institution from the public institution to the community, including best practices for ensuring continuity of health insurance coverage or coverage under the State Medicaid plan under title XIX of the Social Security Act, as applicable, and relevant social services; and (B) to carry out, with respect to such an individual, such health care-related transition not later than 30 days after such individual is released from the public institution.

The Stakeholder Group shall consist of at least 24 members: 2 shall be federal members, appointed by the Secretary or his designee. The federal members shall include designees from federal jail and prison systems, which includes the Federal Bureau of Prisons. Federal members will serve as regular government employees.

The Stakeholder Group shall also consist of 22 non-federal members who are representatives of managed care organizations, Medicaid beneficiaries, health care providers, the National Association of Medicaid Directors, state Medicaid agencies, and representatives from local and state prison systems, The Secretary shall appoint one of the members to serve as the Chair. Non-federal members will serve as Special Government Employees.

The Secretary, or his designee, shall appoint all members of the Stakeholder Group (both federal and non-federal), including one of the members to serve as the Chair. The federal and non-federal members shall be appointed to serve for the duration of the time that the Stakeholder Group is authorized to operate. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–21591 Filed 9–30–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,