

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Law enforcement officers	phone call for recruitment & informed consent.	60	1	30/60	30
Law enforcement officers	Initial meeting	60	1	15/60	15
Law enforcement officers	Knowledge survey	60	2	5/60	10
Law enforcement officers	Epworth Sleepiness Scale	60	2	1/60	2
Law enforcement officers	Pittsburgh Sleep Quality Index	60	2	2/60	4
Law enforcement officers	Demographics and work experience	60	1	2/60	2
Law enforcement officers	Sleep diary	60	42	2/60	84
Law enforcement officers	Online training	60	1	150/60	150
Law enforcement officers	Feedback about Training, Barriers, and Influential People.	60	1	5/60	5
Law enforcement officers	Changes in Behaviors after Training	60	1	2/60	2
Law enforcement officers	Actigraph fitting and return	60	3	10/60	30
Total					334

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.
 [FR Doc. 2020-21731 Filed 9-30-20; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3386-CN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice; correction.

SUMMARY: This document corrects a technical error that appeared in the final notice published in the *Federal Register* on September 28, 2020 entitled “Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program.”

DATES: This correction is effective September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786-2441. Shannon Freeland, (410) 786-4348. Lillian Williams, (410) 786-8636.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020-21260 of September 28, 2020 (85 FR 60799-60800), there was a technical error that is identified

and corrected in this correcting document. The provision in this correction document is effective as if it had been included in the document published September 28, 2020. Accordingly, the correction is effective September 28, 2020.

II. Summary of Error

On page 60799, in the **DATES** section of the notice, the phrase “takes effect October 1, 2020 through October 1, 2024” should be replaced with the phrase “September 28, 2020-September 28, 2024.”

III. Correction of Error

In the *Federal Register* of September 28, 2020, in FR Doc. 2020-21260, on page 60799, in the 2nd column, in the **DATES** section, the phrase “takes effect October 1, 2020 through October 1, 2024” is corrected to read “September 28, 2020-September 28, 2024.”

Dated: September 28, 2020.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2020-21766 Filed 9-28-20; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1517]

The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” This guidance provides general recommendations regarding the development, evaluation, and use of physiologically based pharmacokinetic (PBPK) analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. The guidance covers how to develop, evaluate, and apply PBPK models for biopharmaceutics-related uses, such as establishing clinically relevant dissolution specifications and quality risk assessment for postapproval manufacturing changes.

DATES: Submit either electronic or written comments on the draft guidance by November 30, 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-2020-D-1517] for "The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls." 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 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. 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: Paul Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 21, Rm. 1628, Silver Spring, MD 20993-0002, 301-796-4874.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls." This draft guidance provides general recommendations regarding the development, evaluation, and use of PBPK analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. PBPK analyses use models and simulations that combine physiology, population, and drug characteristics to mechanistically describe the pharmacokinetic and/or pharmacodynamic behaviors of a drug product.

Submission of these analyses to FDA is discussed in the guidance for industry entitled "Physiologically Based Pharmacokinetic Analyses—Format and Content" (available at <https://www.fda.gov/media/101469/download>). However, the application of PBPK modeling in support of drug product development is an evolving field. FDA recognizes this challenge and encourages the development and use of new tools and approaches for linking pharmaceutical quality to clinical performance.

Advances in modeling and simulation have enabled the integration of factors such as the physicochemical properties of the active pharmaceutical ingredient, dissolution data, and the physiology of the gastrointestinal tract into the development of PBPK models. As such, PBPK modeling has become a promising tool in predicting systemic drug exposure of oral drug products.

PBPK analyses for biopharmaceutics applications combine dissolution modeling, biopredictive dissolution profiles, or other in vitro testing inputs with PBPK modeling strategies to quantitatively describe the differential and potential interactions of formulation variants with the body and their effect on drug exposure.

This guidance describes recommended PBPK model structure, which provides a mechanistic framework of drug oral absorption by representing the in vivo drug absorption process and accounting for the relevant

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](https://www.regulations.gov) 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://](https://www.regulations.gov)

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