

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following 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., as amended, and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 13-129, NIOSH Member Conflict Special Emphasis Panel.

*Date:* October 25, 2018.

*Time:* 1:00 p.m.–5:00 p.m. EST.

*Place:* Teleconference.

*Agenda:* To review and evaluate grant applications.

*For Further Information Contact:* Nina Turner, Ph.D., Scientific Review Officer, Office of Extramural Programs, 1095 Willowdale Road, Morgantown, WV 26506, (304) 285-5976; [nxt2@cdc.gov](mailto:nxt2@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2018-19077 Filed 8-31-18; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-3969]

#### Physiologically Based Pharmacokinetic Analyses—Format and Content; 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 final guidance for industry entitled “Physiologically Based Pharmacokinetic Analyses—Format and Content.” This guidance outlines the recommended format and content for a sponsor or applicant to submit physiologically based pharmacokinetic (PBPK) analyses to FDA to support applications including, but not limited to, investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs). This guidance does not address methodological considerations and best practices for the conduct of PBPK modeling and simulation or the appropriateness of PBPK analyses for a particular drug or a drug product.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 4, 2018.

**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-2016-D-3969 for “Physiologically Based Pharmacokinetic Analyses—Format and Content.” 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 about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/>

[fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf](https://www.fda.gov/oc/2015-09-18/pd/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 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. 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:** Xinyuan Zhang, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2128, Silver Spring, MD 20993-0002, 240-402-7971.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a final guidance for industry entitled "Physiologically Based Pharmacokinetic Analyses—Format and Content." A PBPK analysis uses models and simulations that combine physiology, population, and drug characteristics to mechanistically describe the pharmacokinetic behaviors of a drug or drug product. Throughout a drug's life cycle, PBPK model predictions can be used to support decisions on whether, when, and how to conduct certain clinical pharmacology studies, and to support dosing recommendations in product labeling. Because of the lack of regulatory guidance, the format and content of PBPK analysis reports that are submitted to FDA vary significantly. The goal of this guidance is to standardize the content and format of these reports to facilitate FDA's efficient assessment, consistent application, and timely decision making during regulatory review.

This guidance outlines the recommended format and content for a sponsor or applicant to submit PBPK analyses to FDA to support applications

including, but not limited to, INDs, NDAs, BLAs, and ANDAs. This guidance does not address methodological considerations and best practices for the conduct of PBPK modeling and simulation or the appropriateness of PBPK analyses for a particular drug or a drug 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 "Physiologically Based Pharmacokinetic Analyses—Format and Content." 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. This guidance is not subject to Executive Order 12866.

#### **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in 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. 3501-3520). The collection of information in 21 CFR 314.50(d) has been approved under OMB control number 0910-0001.

#### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: August 27, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Food and Drug Administration**

**[Docket No. FDA-2014-N-1048]**

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 4, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0485. Also include the FDA docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### **Medical Device Labeling Regulations—21 CFR Parts 800, 801, and 809**

*OMB Control Number 0910-0485—Extension*

Section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 of the FD&C Act require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices on the labels or labeling for the devices.

Section 502(b) of the FD&C Act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may, however, grant an exemption if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific