Control and Prevention, 1600 Clifton Road NE., M/S E–07, Atlanta, Georgia 30333, telephone (404) 639–8317; Email: *zkr7@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.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2014–02859 Filed 2–10–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates:

8:30 a.m.–4:30 p.m., March 5, 2014
8:30 a.m.–12:00 p.m., March 6, 2014

Place: CDC, 1600 Clifton Road NE., Tom Harkin Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30333. This meeting will also be Webcast, please see information below.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

Matters To Be Discussed: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include the CMS implementation of Individualized Quality Control Plan (IQCP) as a new CLIA quality control option based on risk management for laboratories performing nonwaived testing; CDC's strategic priority for strengthening public health and health care collaborations; and quality improvement tools for managing laboratory testing in ambulatory settings.

Agenda items are subject to change as priorities dictate.

Webcast: The meeting will also be Webcast. Persons interested in viewing the Webcast can access information at: *http://wwwn.cdc.gov/cliac/default.aspx.*

Online Registration Required: All people attending the CLIAC meeting in-person are required to register for the meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for international registrants. Register at *http://wwwn.cdc.gov/cliac/default.aspx* by scrolling down and clicking the appropriate link under ''Meeting Registration'' (either U.S. Citizen Registration or Non-U.S. Citizen Registration) and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than February 26, 2014 for U.S. registrants and February 19, 2014 for international registrants.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible. *Oral Comments:* In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least one week prior to the meeting date. *Written Comments:* For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be provided to the contact person below, and will be included in the meeting's Summary Report.

Availability of Meeting Materials: To support the green initiatives of the federal government, the CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIAC Web site on the day of the meeting for materials. **Note:** If using a mobile device to access the materials, please verify that the device's browser is able to download the files from the CDC's Web site before the meeting. *http://wwwn.cdc.gov/cliac/cliac_meeting_all_documents.aspx* Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An internet connection, power source and limited hard copies may be available at the meeting location, but cannot be guaranteed.

Contact Person for Additional Information: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Programs, Standards, and Services, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone (404) 498–2741; or via email at *NAnderson@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 CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–02858 Filed 2–10–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0129]

Application of Physiologically-Based Pharmacokinetic Modeling To Support Dose Selection; Notice of Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public workshop entitled ''Application of Physiologically-Based Pharmacokinetic (PBPK) Modeling to Support Dose Selection.'' The purpose of the workshop is to obtain input on scientific approaches for the conduct and assessment of physiologically-based pharmacokinetic (PBPK) modeling within the framework of drug development and regulatory decisionmaking. The input from the workshop may be used to refine FDA's thinking on the various applications of PBPK. Preliminary elements of a draft concept paper will be presented to facilitate discussion at this public workshop.

DATES: The workshop will be held on March 10, 2014, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the

workshop must register by February 24, 2014. Please submit either electronic or written comments by April 10, 2014, to receive consideration.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Rm. 2047, Silver Spring, MD 20993. Participants must enter through Building 1 and undergo security screening. For parking and security information, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Please submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the corresponding docket number found in brackets in the heading of this notice. A transcript of the workshop will be available for review at the Division of Dockets Management and at *http://www.regulations.gov* approximately 30 days after the public workshop (see section VI of **SUPPLEMENTARY INFORMATION**).

FOR FURTHER INFORMATION CONTACT: Ping Zhao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3182, Silver Spring, MD 20993, 301–796–3774, FAX: 301–847–8720, email: *ping.zhao@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Title I of FDASIA reauthorizes the Prescription Drug User Fee Act (PDUFA) and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represent FDA's commitments during fiscal years 2013–2017. These commitments are fully described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (''PDUFA Goals Letter''), which is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf*. Section IX of the PDUFA Goals Letter, entitled ''Enhancing Regulatory Science and Expediting Drug Development,'' includes provisions to promote innovation through enhanced communication between FDA and sponsors during drug development. As part of this enhanced communication, FDA made a commitment to hold a public workshop to: (1) Engage stakeholders in a discussion of current and emerging scientific approaches and applications for the conduct of PBPK modeling and simulations and (2) to facilitate stakeholder input regarding the utility of PBPK during drug development and regulatory review. The public workshop announced by this document will fulfill this commitment.

PBPK modeling is a mathematical modeling technique for predicting drug behavior in humans. A PBPK model takes information about a drug's physical, chemical, and other properties, as well as information about processes in the body, and turns them into mathematical equations to predict what will happen when a patient takes the medication. Consequently, PBPK models may be a useful platform in risk assessment during drug development.

II. Purpose and Scope of the Workshop

The objectives of the workshop are to:

1. Share and discuss best practices in the use of PBPK to inform dose selection in specific patient populations, such as patients with renal or hepatic impairment, pediatric patients, elderly patients, and patients with genetic variation,

2. Discuss the current state of knowledge and share current FDA experience regarding important criteria for evaluating the adequacy of PBPK models for intended uses, as well as criteria for considering modeling results when making regulatory decisions,

3. Obtain input on specific issues identified by FDA on the conduct of PBPK analysis.

Since the 1970s PBPK modeling and simulation has been routinely used in toxicology to assess the risk of environmental toxins that cannot be safely studied in humans. In the past decade, PBPK models have increasingly been applied to complex drug development issues that cannot be evaluated in a clinical trial or to issues that can be reliably assessed *in silico,* thereby minimizing the need for costly clinical trials. These types of applications of PBPK are submitted to FDA for regulatory review. As a result, FDA is looking to adopt a rigorous approach to the review of PBPK submissions and the conduct of *de novo* PBPK analysis to support regulatory review. FDA also wishes to be transparent regarding its evidentiary standards and how it weighs the evidence of a PBPK simulation in arriving at a decision or regulatory action.

The public workshop will focus on the use of PBPK models for assessing the effect of various intrinsic and extrinsic factors in order to inform dose optimization. FDA acknowledges, however, that PBPK can be used to support decision making through the entire life cycle of drug development, including preclinical and clinical evaluations.

The input from the workshop may be used to refine FDA's thinking on use of PBPK in determining proper dosage and may lead to the development of a draft guidance for industry. There is currently no FDA guidance on this topic. Specifically, this guidance would describe FDA's view of criteria considered important when evaluating the strength and quality of evidence provided by a PBPK analysis.

FDA will also be preparing a concept paper that will propose best practices and principles for the use of PBPK modeling in drug development and regulatory review. Preliminary elements of this document will be presented at the public workshop by FDA to elicit comments and facilitate discussion. The paper will incorporate the workshop outcomes, then the public will be invited to comment through a public docket.

III. Scope of Public Input Requested

FDA seeks input on a range of topics related to the conduct of PBPK modeling and simulation by pharmaceutical industries and by FDA and on the interpretation and use of simulations when evaluating risk in the regulation of pharmaceutical products. These include:

1. Predictive performance of PBPK models for a specific aim

2. Identification of knowledge gaps in the specific application of PBPK simulation to replace a clinical trial:

a. Criteria for the adequacy of a PBPK model for a specific aim
b. Biological plausibility and predictive performance
c. Model validation and statistical considerations

3. Presentation of simulations in approved product labeling (labeling):

a. When should PBPK simulations be included in drug labeling?

b. What is the best format for presenting PBPK simulations in different sections of the labeling?

c. How should uncertainty in simulations be presented in the labeling?

IV. Attendance and Registration

The FDA Conference Center at the White Oak Campus is a Federal facility with security screening and limited seating. Individuals who wish to attend the public workshop must register on or before February 24, 2014, by visiting *https://www.surveymonkey.com/s/MW5WZDW* and contacting Ping Zhao (see **FOR FURTHER INFORMATION CONTACT**). Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the workshop will be based on space availability.

During the workshop, time will be designated for questions and answers throughout the day and for general comments and questions from the audience following the panel discussions.

In this **Federal Register** document, FDA has included specific issues that will be addressed by the panel. If you wish to address one or more of these issues in your presentation, please indicate this at the time you register so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 2 weeks before the workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* (select this workshop meeting from the events list).

If you need special accommodations because of a disability, please contact Ping Zhao (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

A live webcast of this workshop will be viewable at *https://collaboration.fda.gov/pbpk/* on the day of the workshop. A video record of the workshop will be available at the same web address for 1 year.

V. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

VI. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (see **ADDRESSES**) and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be made available in either hard copy or on CD–ROM upon submission of a Freedom of Information request. Send requests to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02883 Filed 2–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program. OMB No. 0915–0247 Revision.

Abstract: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106–129 and reauthorized by Public Law 109–307 to provide federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs, and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the **Federal Register** regarding Sections 5503, 5504, 5505, and 5506 of the Affordable Care Act of 2010, Public Law 111–148 on Wednesday, November 24, 2010. This final rule included policy changes on counting resident time in non-provider settings, counting resident time for didactic training, and the re-distribution of resident caps. It required modification of the data collection forms within the CHGME Payment Program application. The necessary modifications were made and received OMB clearance on June 30, 2012.

On September 30, 2013, CMS published revised forms on their Web site, requiring additional modifications of the data collection forms in the CHGME Payment Program application. The CHGME Payment Program application forms have been adjusted to accommodate the most recent CMS policy changes. These changes require OMB approval.

Need and Proposed Use of the Information: Data are collected on the number of full-time equivalent residents in applicant children's hospitals' training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that