

Leroy A. Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

[FR Doc. 2018-07016 Filed 4-5-18; 8:45 am]

BILLING CODE 4163-18-P

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)—RFA-CE-18-002, Evaluation of Policies for the Primary Prevention of Multiple Forms of Violence.

Dates: May 23, 2018 and May 24, 2018.

Time: 9:00 a.m.–5:00 p.m., EDT.

Place: DoubleTree by Hilton Hotel Atlanta—Buckhead, 3342 Peachtree Road NE, Atlanta, GA 30326.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, Georgia 30341, Telephone: (404)639-0913; Email: mwalters@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 Baker,

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

[FR Doc. 2018-07051 Filed 4-5-18; 8:45 am]

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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.

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Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CK18-001, Epicenters for the Prevention of Healthcare-Associated Infections (HAIs); Cycle II Multicenter Program Studies and CK18-003, Determining and Monitoring Health Conditions Among US-Bound Refugees and Other Globally Mobile Populations.

Date: May 9, 2018.

Time: 10:00 a.m.–3:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30329, (404) 718-8833, gca5@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 Baker,

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

[FR Doc. 2018-07053 Filed 4-5-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0791]

Exposure-Response Analysis in Drug Development and Regulatory Decision Making; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Prescription Drug User Fee Act of 2017 (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA, highlights the goal of advancing model-informed drug development (MIDD). Exposure-response analysis is a MIDD strategy that has been used in drug development and regulatory decision making. The Food and Drug Administration (FDA or Agency) is opening a docket to receive public comments on experience leveraging exposure-response analysis since publishing the guidance for industry (GFI) entitled “Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications,” which was announced in the **Federal Register** on May 6, 2003. Specifically, the Agency wants to identify areas of scientific policy that may need further clarity or elaboration, as well as any obstacles that prevent use of exposure-response analyses in drug development and regulatory review.

DATES: To ensure that the Agency considers your input, submit either electronic or written comments by July 5, 2018.

ADDRESSES: You may submit comments as follows. Electronic comments must be submitted on or before July 5, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery date service acceptance receipt is on or before that date:

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-2018-N-0791 for "Exposure-Response Analysis in Drug Development and Regulatory Decision Making; Request for Comments." 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>.

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.

FOR FURTHER INFORMATION CONTACT:

Kevin Krudys, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3110, Silver Spring, MD 20993-0002, 301-796-3859, OCP_EPPM_STAFF@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 6, 2003, FDA issued a GFI entitled "Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications" (available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072109.pdf>) (68 FR 24004). This guidance provides recommendations for sponsors of investigational new drugs (INDs) and applicants submitting new drug applications (NDAs) or biologics license applications (BLAs) on the use of exposure-response analyses in the development of drugs, including therapeutic biologics. Since then, FDA and drug developers have gained a wealth of experience performing exposure-response analyses and leveraging the results to influence drug development and inform regulatory review. Additionally, obstacles that limit the routine application and acceptance of exposure-response analyses to address key drug development and regulatory decisions have since been identified. Given that PDUFA VI goals highlight advancing MIDD, FDA wants to capture the public's experience to inform future efforts on providing additional clarity, new insights, and updated

recommendations for employing exposure-response analyses in drug development. To achieve these ends, FDA is opening the docket "Exposure-Response Analysis in Drug Development and Regulatory Decision Making; Request for Comments" to give interested parties an opportunity to identify areas of scientific policy that may need further clarity or elaboration, as well as any obstacles preventing use of exposure-response analyses in drug development and regulatory review.

II. Additional Issues for Consideration: Request for Information and Comments

Interested persons are invited to provide detailed information and comments on the use of exposure-response analysis in drug development and regulatory review. FDA is particularly interested in responses to the following questions:

1. In general, are there any aspects of the 2003 GFI entitled "Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications" that merit further elaboration? Additionally, are there any new topic areas that should be addressed?

2. What are best practices for conducting exposure-response analysis that can be generally applied across development programs and regulatory submissions? Input on best practices can include any of the following topic areas:

- Planning and design (*e.g.*, data considerations, assumption setting);
- Analytical approaches (*e.g.*, exposure and response metrics, choice and inclusion of predictors, methods for addressing confounding factors);
- Model evaluation and qualification (*e.g.*, goodness-of-fit, assessment of model risk, impact on regulatory decisions); and
- Communication of results and impact on subsequent drug development or regulatory decisions.

3. What attributes of an exposure-response analysis are critical to effectively inform a drug development or regulatory decision? Additionally, what are the main obstacles preventing widespread acceptance of exposure-response analyses?

4. During which stages of drug development would it be most productive to interact with the FDA regarding exposure-response analysis planning? What type of feedback would be useful to inform exposure-response analyses and to reduce uncertainty in regulatory acceptance?

FDA will consider all information and comments submitted.

III. Electronic Access

Persons with access to the internet may obtain the 2003 GFI entitled "Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications" at either <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072109.pdf> or <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: April 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-07028 Filed 4-5-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1324]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Board to the Food and Drug Administration. The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board advises the Agency on keeping pace with technical and scientific developments, including in regulatory science; provides input into the Agency's research agenda; and advises on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs. The meeting will be open to the public.

DATES: The meeting will be held on April 23, 2018, from 9 a.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be

webcast. The link for the webcast is available at <https://collaboration.fda.gov/scienceboard2018/>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Rakesh Raghuvanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301-796-4769, rakesh.raghuvanshi@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The Science Board will hear a report from the Center for Biologics Evaluation and Research Program Review Subcommittee; hear about FDA's Patient Affairs Initiative; and discuss how the Agency can leverage its existing tools and authorities, and work with stakeholders, to better address the complex scientific, public health, and technology challenges it faces today.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 18, 2018. Oral

presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 13, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rakesh Raghuvanshi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-07105 Filed 4-5-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0362]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.