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]

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)—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]

BILLING CODE 4163–18–P

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