

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Occupational Safety and Health Education and Research Centers (ERC) PAR 10–217, initial review.

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 aforementioned meeting:

Times and Dates:

8:00 a.m.–5:00 p.m., February 26, 2013 (Closed).

8:00 a.m.–5:00 p.m., February 27, 2013 (Closed).

8:00 a.m.–12:00 p.m., February 28, 2013 (Closed).

Place: Renaissance Atlanta Midtown Hotel, 866 W. Peachtree Street, NW., Atlanta, Georgia 30308, Telephone: (678) 412–2400.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Occupational Safety and Health Education and Research Centers (ERC) PAR 10–217.”

Contact Person for More Information: George Bockosh, M.S., Scientific Review Officer, CDC/NIOSH, 626 Cochran Mill Road, Mailstop P–05, Pittsburgh, Pennsylvania 15236, Telephone: (412) 386–6465; Joan Karr, Ph.D., Scientific Review Officer, CDC/NIOSH 1600 Clifton Road, Mailstop E–74, Atlanta, Georgia 30333, Telephone: (404) 498–2506.

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.

Dated: December 4, 2012.

Elaine L. Baker,

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

[FR Doc. 2012–29908 Filed 12–10–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Medical Devices: The Pre-Submission Program and Meetings With FDA Staff

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 January 10, 2013.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and Title: “Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.” Also, include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@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.

Guidance on Medical Devices: Pre-Submission Program and Meetings with FDA Staff—(OMB Control Number 0910–NEW)

This guidance describes the Pre-Submission program for medical

devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission Package and procedures that should be followed for meetings between CDRH and CBEB staff and industry representatives or application sponsors. When approved by OMB, this guidance document will supersede “Pre-IDE Program: Issues and Answers—Blue Book Memo D99–1” dated March 25, 1999.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA’s feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission Packages in order to implement this voluntary submission program.

Over time, the FDA pre-investigational device exemption (pre-IDE) program evolved to include feedback on premarket approval (PMA) applications, humanitarian device exemption applications, and 510(k) submissions, as well as to address questions related to whether a clinical study requires submission of an IDE. During discussions with representatives of the medical device industry in the development of the Agency’s recommendations for Medical Device User Fee Amendments 2012 (MDUFA III), both the industry and the Agency agreed that the Pre-Submission (formerly pre-IDE) process provided important additional transparency to the IDE and premarket review processes. In response, the Secretary’s 2012 Commitment Letter to Congress (MDUFA III Commitment Letter) included FDA’s commitment to institute a structured process for managing Pre-Submissions.

To fulfill the Secretary’s commitment to the industry, this final guidance: (1) Describes the Pre-Submission program (formerly the IDE program) for medical devices reviewed in CDRH and CBEB; (2) assists device manufacturers and their representatives who seek meetings with the FDA by providing guidance and recommendations regarding information that should be included in a Pre-Submission Package; and (3) provides guidance as to the