(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 review, discussion, and evaluation of applications received in response to Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 1.

For Further Information Contact: Joan Karr, PhD, Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS–K38, Atlanta, GA 30341, Telephone 770.488.2597.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 17, 2004.

Alvin Hall,

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

[FR Doc. 04–11534 Filed 5–20–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4

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:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4.

Times and Dates: 7 p.m.–7:30 p.m., June 10, 2004 (Open). 7:30 p.m.–10 p.m., June 10, 2004 (Closed). 8 a.m.–5 p.m., June 11, 2004 (Closed).

Place: Sheraton Midtown Atlanta Hotel at Colony Square, 188 14th Street at Peachtree, Atlanta, GA 30361, Telephone 404.892.6000.

Status: Portions of 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 review, discussion, and evaluation of applications received in response to Cooperative Agreements Program Announcement Number 00075, Association of American Medical Colleges, Program Announcement Number 99122, Association of Schools of Public Health, and Program Announcement Number 97014, Association of Teachers of Preventive Medicine, Research Project Areas—Panel 4.

Contact Person for More Information: Joan F. Karr, Ph.D., Scientific Review Administrator, Public Health Practice Program Office, Centers for Disease Control, 4770 Buford Highway, NE., MS–K38, Atlanta, GA 30341, Telephone 770.488.2597.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 17, 2004.

Alvin Hall,

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

[FR Doc. 04–11535 Filed 5–20–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0538]

Guidance for Industry and Food and Drug Administration Staff: Food and Drug Administration and Industry Actions on Premarket Notification Submissions: Effect on Food and Drug Administration Review Clock and Performance Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment.'' This guidance describes how FDA will assess its performance in the premarket notification (510(k)) program relative to the goals that accompany the authorization of medical device user fees. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues: Heather Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 143.

For biologics issues: Leonard Wilson, Center for Biologics Evaluation and Research (CBER) (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), signed into law on October 26, 2002, allows FDA to assess user fees for certain premarket reviews. Performance goals, referenced in the statute, accompany the authorization of medical device user fees. These goals represent a realistic

projection of what CDRH and CBER can accomplish with industry cooperation.

The guidance describes premarket review cycle and decision actions and performance goals for premarket notification submissions (510(k)s). This guidance document is immediately in effect because the agency needs to provide guidance on how it intends to address the performance goals it has committed to meeting. On February 4, 2003, FDA published a notice in the **Federal Register** (68 FR 5643) to establish a public docket (02N–0534) so that we could share information on the implementation of MDUFMA and to provide interested persons an opportunity to share their views. On December 3, 2003, the agency held an open public meeting to update its stakeholders on its progress in implementing the new law, discuss some of MDUFMA's more challenging provisions, and obtain input from interested parties. During the drafting of this guidance, the agency specifically solicited comments to the docket on several aspects of the document in recognition of the interest in this issue. The agency has considered all comments received to date and will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on 510(k) review cycle and decision actions and performance goals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment'' by fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1219) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations premarket approval applications (21 CFR part 807, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11503 Filed 5–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. The proposed information collection was previously published in the **Federal Register** on May 23, 2002, page 36202. No public comments were received. The purpose of this notice is to allow and additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, and information that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants. *Type of Information Collection Request:* New request. *Need and Use of Information Collection:* The information collected in these surveys will be used by the Office of Extramural research to evaluate the re-engineering initiatives, including the Modular Grant Application Process and initiatives under the NIH Roadmap, Initiative, intended to facilitate application and award of Federal assistance programs administered by the NIH Modular Application/Grant process has been in effect for two years. At the outset of its implementation, the community was advised that the process would reduce administrative burden by focusing the efforts of investigators, institutional officials, and National Institutes of Health (NIH) staff on the science of the application. The NIH now believes it is an appropriate time to determine if these objectives have been met. *Frequency of response:* On occasion. *Affected Public:* Institutional Officials, Principal Investigators (PI's), Peer Reviewers, Program and Grants Management Staff, Institute Budget Officers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 1,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:*