Dated: January 29, 2003.

Alvin Hall,

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

[FR Doc. 03–2494 Filed 2–3–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Conference Call Meeting

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 Federal advisory committee conference call meeting.

Name: Advisory Committee on Immunization Practices (ACIP).

Time and Date: 2 p.m.–2:30 p.m., Eastern Time, January 29, 2003.

Place: The conference call will originate at the National Immunization Program (NIP), in Atlanta, Georgia. Please see ''Supplementary Information'' for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The Advisory Committee on Immunization Practices will convene by conference call to discuss the number of needle pricks to use when administering the smallpox vaccine.

SUPPLEMENTARY INFORMATION: This conference call is scheduled to begin at 2 p.m., Eastern Standard Time. To participate in the conference call, please dial 1–800–497–1934 and reference conference code 2978861. You will then be automatically connected to the call.

As provided under 41 CFR 102–3.150(b), the public health urgency of this agency business requires that the meeting be held prior to the first available date for publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Demetria Gardner, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE, (E–61), Atlanta, Georgia 30333, telephone 404/639–8096, fax 404/639–8616.

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 CDC and ATSDR.

Dated: January 29, 2003.

Alvin Hall,

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

[FR Doc. 03–2491 Filed 2–3–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0355]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device Recall Authority'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 13, 2002 (67 FR 68876), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0432. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2600 Filed 2–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0534]

Medical Device User Fee and Modernization Act of 2002; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). FDA is establishing this docket in order to provide an opportunity for all interested persons to provide information and share views on the implementation of MDUFMA.

DATES: Submit written or electronic comments at any time.

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

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION: MDUFMA (Public Law 107–250) amends the Federal Food, Drug, and Cosmetic Act to provide FDA important new responsibilities, resources, and challenges. MDUFMA was signed into law October 26, 2002. MDUFMA has three particularly significant provisions:

• User fees for premarket reviews. Premarket approval applications (PMAs), product development protocols (PDPs), biologics license application (BLAs), premarket reports, certain supplements, and 510(k)s are now subject to fees. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of ambitious performance goals that will provide patients earlier

access to safe and effective technology, and will provide more interactive and rapid review to the medical device industry. A small business (sales and receipts of $30 million or less) may pay a reduced fee.

• Establishment inspections may be conducted by accredited persons (third-parties) under carefully prescribed conditions.

• New regulatory requirements for reprocessed single-use devices, including provisions establishing a new category of premarket submission, the premarket report, and provisions requiring the submission of additional data on devices now being reprocessed.

MDUFMA makes several other significant changes that are less complex or have a narrower scope than the major changes discussed previously. These include the following:

• The review of combination products (products that combine elements of devices, drugs, or biologics) will be coordinated by a new office in the Office of the Commissioner of Food and Drugs.

• Electronic labeling is authorized for prescription devices intended to be used in health care facilities.

• FDA may require electronic registration of device establishments, when feasible.

• The law now explicitly provides for modular review of PMAs.

• New provisions concerning devices intended for pediatric use, including provisions for pediatric experts on advisory panels and the development of guidance for clinical trials involving pediatric populations.

• The manufacturer of a device must be identified on the device itself, with certain exceptions.

A letter from the Secretary of Health and Human Services that accompanies the user fee legislation sets forth the performance goals the agency has pledged to meet over the next 5 years. These goals represent the improvements FDA's device review program can achieve, monitor, and meet with industry cooperation. To help meet these performance goals, FDA will need to develop clear definitions of terms such as ''panel-track supplement,'' ''180-day supplement,'' and ''real-time supplement.'' The agency will also need to develop a policy to define when bundling multiple devices, device modifications, or indications for use into a single submission is appropriate versus when separate applications should be submitted.

FDA invites interested persons to submit comments on any or all of the previous issues, as well as other provisions of the new law. (A copy of the statute is available on the agency's MDUFMA Web site at *http://www.fda.gov/cdrh/mdufma/index.html*). FDA hopes this docket will become an important tool for receiving information from interested parties and for public availability of that information. In the future, FDA expects to use its MDUFMA Web site to request input to the docket from stakeholders on a variety of specific questions and issues related to MDUFMA.

At this time, the agency is particularly interested in receiving comments from stakeholders about several provisions that must be immediately implemented to track and monitor the performance goals FDA has pledged to meet over the next few years. Specifically, the agency is seeking input on the following: (1) Defining the various types of PMA supplements; (2) implementing the modular review program for PMAs; (3) establishing a bundling policy to determine when it is appropriate to bundle multiple devices, device modifications, or indications for use into a single submission; and (4) gathering information for the pediatric device guidance document.

On a related matter, MDUFMA also provides for the education and training of stakeholders to assist the agency in developing training programs. FDA invites comments on: (1) Possible subject matter or areas to be included in training programs for FDA employees or industry and (2) subject matter or courses that industry would be willing to provide to FDA employees. Past examples would include sterilization.

FDA will consider all information and views that it receives during the implementation process. FDA will continue to work with interested parties through a variety of means to obtain as much information as possible to assist in the implementation process.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 29, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2604 Filed 2–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Small Business Town Meeting for Pharmaceutical Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public town meeting.

SUMMARY: The Food and Drug Administration (FDA) (Center for Drug Evaluation and Research and the Central Region and Philadelphia District) is announcing a town meeting for small businesses on FDA requirements for approval and marketing of drug products. Topics for discussion include: Over-the-counter (OTC) monographs, labeling, registration, listing, FDA meetings process, imports and exports, financial incentives, and navigating the FDA Web site. This half day meeting targets small pharmaceutical concerns.

Date and Time: The town meeting will be held on Wednesday, March 5, 2003, from 12 noon to 4 p.m.

Location: The town meeting will be held at the William J. Green Federal Bldg., conference rooms A and B, 2d floor, Sixth and Arch St., Philadelphia, PA.

Contact: Marie Falcone, Industry and Small Business Representative, Food and Drug Administration, Central Region, room 900 U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–597–2120, ext. 4003, FAX 215–597–5798, or e-mail: *mfalcone@ora.fda.gov*.

Registration: To access registration form, see *http://www.fda.gov/cder/meeting/pharmbus2003/default.html*. Send registration information (including name, title, firm name, address, telephone, and fax number) to Marie Falcone by February 14, 2003.

There is no registration fee, however, space is limited, therefore interested parties are encouraged to register early. Registration will close after the meeting slots are filled. Those accepted into the course will receive written confirmation. Registration at the site will be done on a space available basis on the day of the town meeting, beginning at 11 a.m. Please arrive early to ensure prompt registration. Bring photo identification for security check at building entrance. If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Small Business Town Meeting for Pharmaceutical Industry'' town meeting