

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.

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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