presentations should notify the contact person before May 11, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 2006.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. E6–6509 Filed 4–28–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005D–0401]**

### Guidance for Industry and Food and Drug Administration Staff: Compliance With the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' The Medical Device User Fee and Modernization Act 2002 (MDUFMA), as amended by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), requires that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not ''prominent and conspicuous.'' MDUFSA requires that FDA issue guidance no later than 180 days after the date of enactment (August 1, 2005).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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:** Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0106.

**SUPPLEMENTARY INFORMATION:**

### I. Background

MDUFMA (Public Law 107–250) amended section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) to require a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. This labeling provision applied to all devices and all device manufacturers.

On August 1, 2005, MDUFSA (Public Law 109–43) amended section 502(u) of the act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Therefore, section 502(u) of the act, as amended by MDUFSA, no longer sets forth requirements for original equipment manufacturers, unless they also reprocess SUDs. Under the amended provision, if an original device or an attachment to it does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, the manufacturer who reprocesses the SUD may identify itself using a detachable label on the packaging of the device.

Section 2(c)(2) of MDUFSA requires that FDA issue guidance not later than 180 days after the date of its enactment to identify the circumstances under which the identifying mark of a manufacturer of an original device is not ''prominent and conspicuous,'' as used in section 502(u) of the act. On October 11, 2005, FDA issued draft guidance describing the circumstances under which the agency would not consider a manufacturer's mark to be prominent and conspicuous. FDA received several comments on the draft guidance, all of which were considered in finalizing the guidance.

### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' 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 '' Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices'' by fax, 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 (1217) 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 (the PRA) (44 U.S.C. 3501–3520). The collection(s) of information in this guidance were approved under OMB control number 0910–0577.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or 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: April 24, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–6458 Filed 4–28–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program—New**

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) is responsible for the Evaluation of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major national initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuse-related problems in communities; and, (3) build prevention capacity and infrastructure at the State/territory and community levels. Five steps comprise the SPF:

- Step 1: Profile population needs, resources, and readiness to address needs and gaps.
- Step 2: Mobilize and/or build capacity to address needs.
- Step 3: Develop a comprehensive strategic plan.
- Step 4: Implement evidence-based prevention programs, policies, and practices.
- Step 5: Monitor, evaluate, sustain, and improve or replace those that fail.

Under a contract with CSAP, an evaluation team will implement a multi-method quasi-experimental evaluation at national, State, and community levels. Evaluation data will be collected from 26 states receiving grants in 2004 and 2005 and as many as 32 non-grantee states that will serve as a comparison group. The primary evaluation objective is to determine the impact of SPF SIG on the SAMHSA National Outcome Measures (NOMs).

This notice invites comment on state-level and community-level data collection instruments. The instruments for assessing state-level change will be included in an OMB review package submitted immediately after the expiration of the comment period and are the main focus of this announcement. These instruments will be reviewed first by OMB to ensure that state-level data collection occurs as specified in the evaluation plan (on or before June 30, 2006). Because the states have not awarded community-level funding, the evaluators will not initiate community-level data collection until late in 2006. Thus, the community-level survey will be submitted as an addendum approximately one month after the comment period expires. However, the instrument is described in this notice and comments on the instrument are invited.

**State-Level Data Collection**

Two instruments were developed for assessing state-level effects. Both instruments are guides for telephone interviews that will be conducted by trained interviewers three to four times over the life of the SPF SIG award. The *Strategic Prevention Framework Index* will be used to assess the relationship between SPF implementation and change in the national outcome measures. The *State Infrastructure Index* will capture data to assess infrastructure change and to test the relationship of this change to outcomes. Prevention infrastructure refers to the organizational features of the system that delivers prevention services, including all procedures related to planning, data management systems, workforce development, intervention implementation, evaluation and monitoring, financial management, and sustainability. The estimated annual burden for state-level data collection is displayed below in the table.

STATE LEVEL BURDEN ESTIMATE

[Year 1]

| Interview guide | Content description | Number of respondents | Number of responses | Hourly burden per response | Total hourly burden |
|---|---|---|---|---|---|
| SPF Implementation Index. | SEW activities, indicators for each SPF step, including cultural competence throughout all five steps. | 26 | 1 | 3 | 78 |