of the bases for making the assignment or designation decision. Most information required by the proposed regulation is already required for premarket applications affecting drugs, devices, biological and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3	28	1	28	24	672

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15699 Filed 6–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0226]

Draft Guidance for Industry and FDA Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices.'' Section 301 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) requires that a device, or an attachment to the device, bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol that identifies the manufacturer. Section 301 becomes effective on April 26, 2004, for devices introduced or delivered for introduction into interstate commerce after that date. This draft guidance provides that the agency, in the exercise of enforcement discretion, does not intend to object if a manufacturer has not yet fully implemented the changes required by section 301 of MDUFMA for devices introduced or delivered for introduction into interstate commerce after April 26, 2004, for a period of up to 18 months after FDA issues final guidance on its interpretation and implementation of section 301. This draft guidance is neither final, nor is it in effect at this time.

DATES: Submit written or electronic comments by September 22, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices'' 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. Submit written comments concerning this draft 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.* See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

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, 301–594–4692, or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0799.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) added a provision to the Federal Food, Drug, and Cosmetic Act that requires 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 that identifies the manufacturer. The requirement may be waived based on a determination that compliance is not feasible or would compromise the provision of reasonable assurance of safety and effectiveness for the device. Failure to comply with the new requirement misbrands the device (section 301 of MDUFMA (21 U.S.C. 352(u))). This provision is effective April 26, 2004, with respect to devices introduced or delivered for introduction into interstate commerce after that date.

This draft guidance provides that, in the exercise of enforcement discretion, FDA does not intend to object if a manufacturer has not yet fully implemented the changes required by section 301 of MDUFMA for devices introduced or delivered for introduction into interstate commerce after April 26, 2004, the effective date of the provision, for a period of up to 18 months after FDA issues final guidance on the implementation of section 301.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the compliance with section 301 of MDUFMA. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

To receive the draft guidance for industry and FDA staff entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002–Identification of Manufacturer of Medical Devices'' 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 (1217) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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.*

Dated: June 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15731 Filed 6–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999P–1656]

Posting Warning Letter Responses on FDA's Web Site; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) plans to implement a 6-month pilot program in which we (FDA) will post on our Internet Web site certain responses to warning letters. The pilot program is part of our ongoing efforts to keep the public informed regarding agency activities and to make information publicly available. During this pilot, we will post copies of certain responses to warning letters if the recipient requests that the response be posted on our Web site and submits the response in an appropriate electronic format. We will review the responses and redact certain information to ensure that the responses comply with protections available under the Freedom of Information Act (FOIA).

DATES: The pilot program will begin on September 22, 2003.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

FDA traditionally receives many requests under FOIA (5 U.S.C. 552) for warning letters issued to FDA-regulated entities. In compliance with the Electronic Freedom of Information Act Amendments of 1996 (EFOIA), we post on our Web site warning letters that are, or are likely to be, frequently requested documents under FOIA. Updated information regarding a specific issue discussed in a warning letter, however, may not be available on the Web site. In a citizen petition dated May 26, 1999, we were asked to draft regulatory procedures that would require us to promptly post, to the extent permitted under FOIA, agency records related to any previously posted warning letters. The petition requested that this policy extend to agency memoranda or letters that relate, refer, or pertain to any resolution of any of the issues in the warning letters and, where applicable, updates to the firm profile. We declined to post all materials related to warning letters on our Internet Web site, but decided to initiate a 6-month pilot program in which we will post certain responses to warning letters.

II. Pilot Program Description

The pilot program is part of our ongoing efforts to keep the public informed regarding agency activities and to make information available in a manner that is accessible and fair. Accordingly, we plan to test, for 6 months, a pilot program that provides warning letter recipients the opportunity to have their responses to warning letters posted on our Web site. For purposes of this pilot only, we consider warning letter recipients to be the addressee and any other individuals or entities specifically named in a warning letter.

When the pilot program begins, responses submitted to us: (1) With request that the response be posted, and (2) in the format described in the following paragraphs, will be considered for the pilot program. After 180 days, we will evaluate the pilot and determine whether the program should become permanent. However, if we experience undue burden in dealing with the process, find that the process is too resource-intensive, or determine that misleading information is being conveyed to the public as a result of the pilot, we may discontinue the program.

We will post a warning letter recipient's response on our Web site if the recipient: (1) Requests that the response be posted, and (2) submits to us a copy of the response in a word processing format on a disk or CD–ROM. (The disk or CD–ROM should be submitted to the FDA office that issued the warning letter and should be submitted with the response.) We will review the response and redact certain information to ensure that the response complies with protections available under FOIA. For purposes of this pilot program only, we consider a warning letter recipient to be the addressee and any other individual or entity specifically named in a warning letter. If a warning letter recipient wishes to participate in this pilot, the recipient should submit a copy of the response on a computer disk in a word processing format. We will electronically redact and also convert the document to a format that is consistent with 29 U.S.C. 794d. Warning letter recipients submitting a response should clearly identify the warning letter to which they are responding by noting the date of the warning letter and the company(ies) or individual(s) involved.

We reserve the right not to post responses in some cases, such as when a response would likely mislead the public concerning the safety or efficacy of a company's product(s). During this pilot program, we also intend to place a disclaimer on our Web site stipulating the following:

Note: The Food and Drug Administration cannot assure the accuracy of information submitted to the agency without a complete review of the submitted materials and resolution of the issues discussed therein. To make certain information available to the public, the agency has undertaken a pilot program to post responses to warning letters before evaluating the documents and resolving the issues. The responses are redacted to the extent permitted by the Freedom of Information Act.