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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Draft Guidance for Industry and FDA Staff; Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of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 This draft guidance provides that the agency, in the exercise of enforcement discretion, does not intend to object if a manufacturer has not yet fully implemented the changes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

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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 This draft guidance is neither final, nor is it in effect at this time.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 *[insert date 90 days after date of publication in the* **Federal Register***]*.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices" to the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 Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: 6/13/03
June 13, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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