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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

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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: 4/24/06

April 24, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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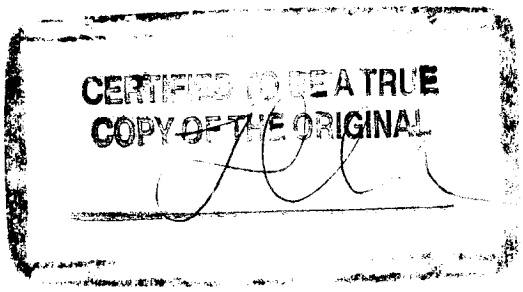
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