Contains Nonbinding Recommendations

Draft - Not for Implementation

Draft Guidance for Industry And FDA Staff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

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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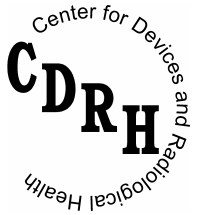
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document that concern devices regulated by the Center for Devices and Radiological Health (CDRH), contact Casper E. Uldriks at 301-594-4692 ext. 162 or at ceu@cdrh.fda.gov. For questions that concern devices regulated by the Center for Biologics Evaluation and Research (CBER), contact Leonard Wilson at (301) 827-0799.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Section 301 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), signed into law by President Bush on October 26, 2002, amends section 502 of the Federal Food, Drug, and Cosmetic Act (the Act) 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 that identifies the manufacturer. The amendment becomes effective on April 26, 2004 (21 U.S.C. 352(u)) for devices introduced or delivered for introduction into interstate commerce after that date.

This draft guidance is to advise 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, the effective date of the provision, for a period of up to 18 months after FDA issues final guidance on its interpretation and implementation of section 301.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) added a provision to the Federal Food, Drug, and Cosmetic Act (the 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.

The new requirement applies to all devices. Devices come in many sizes, shapes, and forms, and are made from many different materials. In the absence of guidance, manufacturers may not be clear as to how to proceed across broad range of devices or whether they are eligible for a waiver. It would be burdensome for industry to go ahead and make what could be considerable investment in device design and production changes prior to FDA issuing guidance on how to comply with section 301 when they might have to change again when FDA does issue guidance. In addition, after FDA issues final guidance on implementation of section 301, manufacturers will need a reasonable period of time to make necessary changes.

III. FDA POLICY

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.

IV. FREQUENTLY ASKED QUESTIONS

1. What does the new provision on identification of manufacturers of medical devices require?

The new provision provides that a device shall be deemed to be misbranded "unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this provision for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device." (Section 301 of MDUFMA, 21 U.S.C. 352 (u)). The provision is effective April 26, 2004, for devices introduced or delivered for introduction into interstate commerce after that date.

2. Why is there a waiver to the requirement?

The new provision recognizes that in some cases it may not be feasible to comply with the requirement to prominently and conspicuously label the device with the manufacturer's name or recognizable symbol. The statute also gives the agency authority to grant a waiver in situations where compliance with the requirement would compromise the safety or effectiveness of the product.

3. Will the agency provide information about how I can apply for a waiver?

Yes. The agency is currently developing guidance on the implementation of the section 301 requirement that will help manufacturers understand when it might be appropriate to apply for a waiver and how to do so. FDA expects to issue that draft guidance this summer. In the meantime, it is not necessary to apply for a waiver because FDA, 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 for devices introduced or delivered for introduction into interstate commerce after April 26, 2004. After the issuance of final guidance, FDA intends to exercise enforcement discretion for a period of up to 18 months so manufacturers will have reasonable time to comply.

4. **What are the time periods when FDA does not intend to object to noncompliance with the new requirement?**

As stated above, the agency, in the exercise of enforcement discretion, does not intend to object if a manufacturer does not comply with the new requirement 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 the implementation of section 301. We will announce in the Federal Register when the final guidance is available.

5. Will there be opportunities to comment on the guidance related to section 301?

Yes, you may comment on this draft guidance regarding compliance. In addition, you will have an opportunity to comment on another draft guidance to be published later on FDA's interpretation and implementation of the new provision.

6. Does this guidance relate to the special labeling requirements MDUFMA put into effect for single use devices (SUDs) that are being reprocessed?

No. Another provision of the MDUFMA requires repressors of SUDs to include specific labeling that clearly states "Reprocessed device for single use. Reprocessed by (reprocessor's name)." The labeling requirement for SUDs only will be addressed through separate guidance.