AMDR
Association of Medical Device Reprocessors

September 22, 2003

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket Number 02N-0534 and 03D-0226; Comments on the Medical Device User Fee and Modernization Act of 2002, Section 301: Identification of Manufacturer of Medical Devices

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the February 4, 2003 publication by the Food and Drug Administration (FDA) of a notice in the *Federal Register*[1] soliciting input on the implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)[2] and the agency's subsequent publication of a draft guidance concerning certain device marking requirements contained in section 301 of MDUFMA.[3] AMDR is a Washington, D.C.-based trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for single use. It is estimated that AMDR members perform approximately 95% of the third-party reprocessing done in the United States. The purpose of these comments is to provide FDA with input on the implementation of section 301, concerning the "identification of the manufacturer of medical devices."

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1 Medical Device User Fee and Modernization Act of 2002; Establishment of a Public Docket, 68 Fed. Reg. 5,643 (Feb. 4, 2003).

2 Pub. L. No. 107-250, 116 Stat. 1588 (codified as amended in scattered sections of Title 21 of the United States Code).

3 Draft Guidance for Industry and FDA Staff; Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of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, 68 Fed. Reg. 37,161 (June 23, 2003) [hereinafter Draft Guidance].

Office 1400 16th Street NW, Suite 400 Washington, DC 20036 **Phone** (202) 518-6796 **Fax** (202) 234-0399 **Web** www.amdr.org

A. Background

In enacting MDUFMA, Congress addressed a variety of issues relevant to the manufacture and distribution of medical devices. Among other things, section 301 of MDUFMA amended section 502 the Federal Food, Drug, and Cosmetic Act to require all medical devices to be marked, "prominently and conspicuously," with the "name of the manufacturer," "a generally recognized abbreviation of such name, or a unique and generally recognized symbol" that identifies the manufacturer.[4] FDA is permitted to waive this requirement if compliance is "not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device."[5]

On June 23, 2003, FDA issued a draft guidance document entitled, "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" [hereinafter Draft Guidance].[6] The Draft Guidance does not contain substantive advice to assist manufacturers in complying with section 301. Rather, the Draft Guidance indicates that the agency is working on such a substantive guidance document and expects to issue it, in draft form, during the summer of 2003.[7] AMDR respectfully requests that the agency consider these comments carefully in the development of that substantive guidance document.

B. Section 301 Applies to All Manufacturers

When Congress was in the process of drafting MDUFMA, original equipment manufacturers (OEMs) urged that the legislation include a provision requiring reprocessed devices to be marked with the name of the reprocessor, so that end-users could more accurately assign responsibility in the event of a device-related problem. FDA sought to expand this provision to apply to *all* devices, not just reprocessed devices. Congress concurred and, accordingly, the final version of section 301 was

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4 Section 301(a) of MDUFMA, codified at 21 U.S.C. § 352(u).

5 *Id.*

6 Draft Guidance, *supra* note 3.

7 By the terms of the statute, section 301's marking requirement becomes effective on April 26, 2004. 21 U.S.C. § 352(u). The June 23 Draft Guidance advises, however, that the agency will exercise its enforcement discretion and will not object to a manufacturer's failure to comply with section 301's requirements "for a period of up to 18 months after FDA issues final guidance on its interpretation and implementation" of the statutory provision. *See* Draft Guidance, *supra* note 3, at 2.

deliberately crafted to apply to "devices," rather than being limited to "reprocessed single-use devices," as with section 302. This decision is emphasized in the legislative history of this provision, which explains, "This Section applies to *all* devices, not just reprocessed single use devices."[8]

It appears that OEMs now recognize that complying with the provisions they once sought to impose only on reprocessors will be tremendously burdensome.[9] It appears that, for this reason, they now are asserting that the marking requirement imposed by section 301 was not intended to apply to them.[10]

These assertions run counter to Congress' documented intent. While AMDR wholeheartedly concurs with the assertions of the OEMs that section 301 will impose significant burdens on manufacturers — especially on small manufacturers such as reprocessors — it is indisputable that Congress intended section 301 to apply to all devices, not just reprocessed devices.

In addition to asserting, erroneously, that section 301 was originally intended to apply only to reprocessed "single use" devices, some OEMs have, in their comments to FDA on this issue, suggested that FDA first implement section 301 with respect to reprocessors, and only later, "as needed," should the agency then move to enforce the requirements against OEMs.[11] Such an approach is not supportable. Reprocessors are subject to all of the regulatory requirements to which OEMs are subject, and the burdens that section 301 imposes are the same for both reprocessors and OEMs. Reprocessors must therefore be regarded as similarly situated to the OEMs for purposes of section 301 and cannot properly be singled out for more heavy-handed enforcement. It is

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8 Medical Device User Fee and Modernization Act of 2002, H. Report 107-728 at 45 (October 7, 2002) (emphasis added).

9 *See, e.g.,* Comments of AdvaMed, at 2 (March 11, 2003) (stating that section 301 "creat[es] unforeseen difficulties for regulated persons and the agency" and "poses a significant burden to industry with little or no apparent benefit"). *See also* comments of the Medical Device Manufacturers Association (MDMA), at 1 (April 11, 2003) (stating that the provision "will impose formidable financial burdens on device manufacturers").

10 *See, e.g.,* Comments of Dental Manufacturers of America (DMA), at 1 (April 7, 2003) (stating that "Section 301 was *inadvertently* applied to all medical devices" (emphasis added)). *See also* comments of AdvaMed, at 2 (April 7, 2003) (stating that the original intent of section 301 was "to apply the requirements only to single use devices that are reprocessed").

11 *See, e.g.,* Comments from Abbott Laboratories, at 2 (April 3, 2003).

well-established that the agency must treat similarly situated parties similarly; to do otherwise is "arbitrary and capricious" and thus in violation of the Administrative Procedures Act.[12] Therefore, AMDR trusts that the agency will reject the OEMs' suggestion and, instead, implement section 301's requirement evenhandedly with respect to all manufacturers.

C. Devices for Which Marking Is Not Feasible Should Be Exempt

At the time the language of section 301 was being drafted, Congress recognized that, in some cases, it would not be feasible to affix an identifying mark or tag and, therefore, added language that states that the requirement can be waived by FDA where marking is "not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device."[13]

With respect to a number of single-use devices that are commonly reprocessed, AMDR agrees with the assertions made in comments submitted by OEMs that many devices are too small to carry an identifying mark, or the surface properties are not conducive to legible printing. Consistent with some OEM comments, AMDR urges FDA to develop a list of device categories that are exempt from the requirements of section 301. (Attached hereto is a list of devices that AMDR believes should be exempt from section 301 requirements.) Although an alternative approach would be to grant exemptions in response to individual petitions from manufacturers, AMDR submits that a case-by-case petition process would be unwieldy and inefficient. For small manufacturers, such as AMDR's member companies, multiple petitions would be a time-consuming and resource-intensive endeavor.

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AMDR appreciates the opportunity to provide FDA with comments on this important matter. Should the agency have any questions regarding the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,

Pamela J. Furman, Esq.
Executive Director

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12 *See, e.g.,* Bracco Diagnostics v. Shalala, 963 F.Supp. 20 (D.D.C. 1997).

13 Section 301(a) of MDUFMA, codified at 21 U.S.C. § 352(u).

cc: Daniel Schultz, FDA
Vincent Ventimiglia, Health Policy Director, Senate Health, Education, Labor and Pensions Committee
John P. Ford, Counsel, House Energy and Commerce Committee
Jeremy Allen, Policy Coordinator, House Energy and Commerce Committee
Jeanne Haggerty, Health Policy Advisor, Congressman Mike Bilirakis
Eleanor Dehoney, Legislative Director, Congressman Sherrod Brown
Ann Witt, Health Advisor, Congressman Henry Waxman

LIST OF DEVICES THAT AMDR BELIEVES SHOULD BE EXEMPT FROM THE MARKING REQUIREMENT

Device Type	CFR
Anesthesia masks	868.5550
Arthroscopic wand/electrode	878.4400 / 888.1100
Bone taps	888.4540
Burrs	888.4540
Carpel tunnel blades	888.4540
Cartilage knives	888.4540
Colorado electrodes	878.4400
Drill bits	878.4820
Endoscopy electrodes	876.4300
ENT shavers	874.4140
ERCP devices	876.5010 / 876.1500
Laser probes/light pipes	886.4390
LoneStar retractor/stays	878.4800
Orthopedic tube harvesters	888.4540
Phacoemulsification tips	886.4670
Saw blades	878.4820
Scissor tips	878.4800
Shavers (arthroscopic)	888.1100