

November 9, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Sir or Madam:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical technology market, I am submitting these comments in response to the Food and Drug Administration's ("FDA's") recently published Draft Guidance for Industry and Staff entitled "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and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 "FDA Guidance Document").<sup>1</sup> MDMA is particularly interested in ensuring that reprocessed single-use devices ("SUDs") are prominently and conspicuously marked, as expeditiously as possible for the protection of the public health.

MDMA agrees with FDA's interpretation of section 502(u) of the Federal Food Drug and Cosmetic Act, as amended by the Medical Device User Fee Stabilization Act ("MDUFSA"). Section 502(u) requires manufacturers of reprocessed SUDs to mark the reprocessed device prominently and conspicuously with the name of the reprocessor, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the reprocessor. Section V.2. of the FDA Guidance Document outlines the effective date for implementing the reprocessor labeling requirements of section 502(u). According to the Guidance Document, if the original equipment manufacturer ("OEM") first marks a device with its name or symbol before August 1, 2006, the reprocessor must mark the reprocessed device by August 1, 2006; if the OEM first marks the device after August 1, 2006, the reprocessor must immediately mark the device. MDMA agrees that the approach described in the FDA Guidance Document clearly reflects the language of the statute and ensures that the legislation's goals of protecting patient health are fulfilled as expeditiously as possible.<sup>2</sup>

Congress has repeatedly recognized that unmarked, reprocessed SUDs may pose significant patient safety risks. When the reprocessor of a SUD is not identified, the FDA is prevented from adequately identifying and controlling the risks posed by reprocessing. FDA's Medical Device Reporting (MDR) regulations are the cornerstone of FDA's postmarketing surveillance system for medical devices. These regulations require manufacturers to report patient injuries and product malfunctions to FDA. This information enables both the manufacturer, and FDA, to identify safety and/or effectiveness problems, and to take any needed corrective action (e.g., product design changes,

---

<sup>1</sup> 70 *Fed. Reg.* 59074 (Oct. 11, 2005).

<sup>2</sup> Case law has held that if statutory language is clear, there is no reason to resort to legislative history. *U.S. v. Gonzales*, 520 U.S. 1, 6 (1997) ("Given the straightforward statutory command, there is no reason to resort to legislative history"); *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253-4 (1992) ("[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there"); *West Virginia University Hospitals, Inc. v. Casey*, 499 U.S. 83, 98-99 (1991) (noting that where the statutory text is unambiguous, it cannot be expanded or contracted by the statements of individual legislators or committees).

recalls, or other notifications to the field) to prevent unnecessary patient injuries. This system cannot work unless the health care providers, the OEM and the FDA can readily identify when and by whom a SUD has been reprocessed. Unless reprocessed devices are clearly marked as such and the reprocessor is clearly identified, the OEM will likely be erroneously identified as the source of a reprocessed device. This may significantly hinder or preclude FDA's ability to identify and address safety and efficacy failures associated with the reprocessed device.

In light of these serious public health concerns, Congress required reproprocessors to mark their reprocessed SUDs by August 1, 2006, within one year after the implementation of the Act. Further, Congress indicated that reproprocessors should mark their devices as soon as possible. Congress suggested that it should not take reproprocessors a year to mark their reprocessed devices and discouraged reproprocessors from taking the entire year to comply. Specifically, in the MDUFSA Report, the Committee stated that “[a]lthough the section 502(u) will first become effective 12 months after the legislation is enacted, the committee believes that it is clear how this section applies to the vast majority of reprocessed devices, and the committee expects reproprocessors to implement its requirements as soon as possible for the devices they reprocess, in the best interest of post-market surveillance and the public health.”<sup>3</sup> In other words, reproprocessors were on notice as of August 1, 2005 for devices currently on the market, and for products under development that the marking of devices is a component of their required product manufacturing, labeling, development, and intake procedures to identify when a previously used device is marked. Reprocessors were given a full 12 months to do this.

The vast majority of the devices that are reprocessed require 510(k) premarket notification clearance prior to marketing. This requires reproprocessors to develop and implement reprocessing procedures; develop and print product labels, labeling, and packaging; and to ensure that their manufacturing processes are in full compliance with FDA's Quality Systems Regulation before the reprocessed device is ever marketed. Marking the device with the reproprocessors name or symbol – in addition to other product labels and labeling that must be developed – is a relatively minor aspect of this process and certainly does not require an additional year to implement after receiving clearance for marketing. There is no justifiable reason for permitting a reprocessor a year of anonymity to hide from regulatory requirements specifically designed to protect patient safety. Under these circumstances, if the concept of allowing reproprocessors an additional year to mark their reprocessed devices had been a part of the discussions between industry, patient advocate organizations, FDA and Congress in developing the MDUFSA amendments – industry and the patient advocate organizations would have strongly objected, and urged Congress not to adopt this approach.

MDMA appreciates this opportunity to comment on the Draft FDA Guidance Document and encourages the FDA to finalize the Guidance Document in its current form, which is consistent with the language of the statute and in the best interest of public safety.

Sincerely,



Mark Leahey  
Executive Director  
Medical Device Manufacturers Association

---

<sup>3</sup> MDUFSA, Public Law 109-43.