ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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April 3, 2003

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

RE: Medical Device User Fee and Modernization Act of 2002
[Docket 02N-0534]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding section 301[1] of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which requires medical devices to bear the name, abbreviation, or symbol of the manufacturer.

We are writing in support of the March 11, 2003 comments on section 301 submitted to the docket by the Advanced Medical Technology Association (AdvaMed). Specifically, we recommend the Agency define the term "manufacturer" broadly in the context of section 301 for the reasons provided by AdvaMed. Furthermore, we urge the Agency to adopt AdvaMed's recommendation that the Agency interpret provision 301 as it was originally intended and that is to apply the requirements to single use devices that are reprocessed.

Alternatively, we recommend the Agency consider a risk-based approach to implementing section 301, focusing first on known single use device types that are

[1] Section 301(a) states, "If it is a device, 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 paragraph 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(b) states, "The amendment made by subsection (a) takes effect 18 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date."

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reprocessed. The Agency could, as originally intended, apply section 301 to single use devices known to be reprocessed, identifying such devices through FDA guidance.[2] As needed, overtime, the Agency could add to the devices covered by section 301. The associated labeling of devices with no known history of reuse, such as intravascular administration sets, *in vitro* diagnostics, and vascular stents, identifies the manufacturer of the device. Unlike reprocessed single use devices, devices with no known history of reuse are not "remanufactured" by another manufacturer. Therefore, such devices have only one manufacturer responsible for the device, as identified in the product labeling.

As FDA implements section 301, we recommend the Agency consider the following items:

1. Defining the word "attachment" as used in section 301
2. Application of the phrase "unique and generally recognized symbol" identifying the manufacturer
3. Product inventory
4. Request for time extension
5. Exemptions for certain medical devices

Defining the word "attachment" as used in section 301

Most simply, a label, containing the manufacturer's name, abbreviation, or recognized symbol, affixed directly to a device is an attachment. While this interpretation may seem obvious to some, we feel it is important for the agency to clarify this interpretation in issuing guidance. Several device types, such as *in vitro* diagnostic reagents, glucose meters, analyte specific reagents, and infusion pumps, contain such labels. Because of the complexity in implementing section 301 it is important for industry to have a clear understanding of how labels can be used to comply with this provision. We recommend FDA provide such clarification in guidance.

Application of the phrase "unique and generally recognized symbol" identifying the manufacturer

We feel it is important for the agency to recognize and acknowledge in forthcoming guidance that a manufacturer may have more than one unique and generally recognized symbol. For example, a manufacturer may have established a unique and generally recognized symbol for devices in a particular product line, such as nutritional products/devices. Practitioners in such areas recognize the entity responsible for the device. Thus, already achieving the intent of section 301. A contrary interpretation of the phrase "unique and generally recognized symbol" would unduly burden device manufacturers who identify their devices in this manner. Furthermore, such an interpretation would require costly replacement of existing symbols, printed, molded, or etched on device product lines, with little or no public health benefit.

Product inventory

As amended by Section 301 of MDUFMA, a device will become misbranded under subsection 502(u) of the Act as of April 26, 2004 unless the device, or an attachment to the device, bears the name, abbreviation, or recognized symbol of the manufacturer.

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[2] *See* U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Guidance on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, Office of Compliance, Division of Enforcement III, August 14, 2000, Appendix A.

The 18-month timeframe to comply with subsection 502(u) creates significant and costly inventory concerns. The following examples create inventory concerns: (1) devices with a shelf-life greater than 18 months manufactured prior to the enactment of MDUFMA, (2) devices manufactured while manufacturers assess the most-cost effective approach for adding the manufacturer's name, and (3) devices manufactured while biocompatibility and functionality testing are conducted to assure safety or effectiveness have not been altered. Confirmation by FDA that devices shipped to distribution centers and warehouses prior to April 26, 2004 have been "delivered for introduction into interstate commerce,"[3] for purposes of section 301, will alleviate these industry concerns.

Request for time extension

We also request the Agency grant an extension of at least 12-months beyond the current deadline of April 26, 2004. In addition to the inventory concerns discussed above, the complexities involved with implementation of section 301 require additional time. Devices must be assessed for the most-cost effective approach to adding the manufacturer name, abbreviation, or symbol. Biocompatibility, functionality, and stability testing may be required to confirm that the addition of the name has no adverse effects on safety or performance. For example, the addition of a dye or etching techniques to identify a device may require safety testing. Manufacturing processes may need to be changed to incorporate new methods for marking devices. These activities require time making it extremely difficult, if not impossible, to comply with section 301 by April 26, 2004. Furthermore, without an exemption for accessories, components, and parts, as discussed below, the magnitude of activities required to implement section 301 increases tremendously. Therefore, we request FDA grant a minimum of a 12-month extension.

Exemptions for certain medical devices

For certain device categories the significant burden of complying with section 301 provides no apparent health benefit. For these devices we request FDA provide an exemption from section 301.

In vitro diagnostics (IVD) devices are an example of a category of devices for which a broad exemption is appropriate. IVDs are not intended for use directly in or on a patient. Moreover, IVDs are subject to specific labeling regulations that conform to the requirements of section 301 and that ensure there is adequate information to enable the end user to identify the person or entity responsible for the device.[4]

We also support a broad exemption for permanent implants, such as stents. In many cases, permanent implants may be physically too small to apply a label. Also, the placement of the name on permanent implants may pose a public health risk by affecting the safety or effectiveness of the product.

FDA should exempt from the requirement of section 301 components and accessories that are packed and distributed in custom-made kits. A manufacturer assembling such kits typically includes medical devices manufactured by that manufacture and related components purchased from various manufacturers. Because these kits are labeled in

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[3] Medical Device User Fee and Modernization Act of 2002, Pub. L. 107-250, § 301(b), 116 Stat. 1616 (2002).

[4] *See* 21 CFR § 809.

accordance with 21 CFR § 801 the provider of the kit is identified. A kit composed of devices and components branded with various manufacturer names could actually cause confusion as to whom to contact with complaints or adverse events.

Accessories, components, and parts are other areas where an exemption is appropriate. A literal application of section 301 to devices will involve requiring manufacturer names on components, parts, or accessories that are sold separately or provided with the finished device, but themselves are not finished devices. We urge FDA not to apply the requirements of section 301 to components, parts, or accessories that, although devices within the meaning of the Act, are not finished products but truly parts of finished devices, which themselves will be identified by manufacturer name.

Additionally, for the reasons provided below, we feel the following devices are eligible for waiver from section 301:

Type of Device	Rationale
CARDIOVASCULAR DEVICES	
• Topical Hemostasis Pads	Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.
• Vascular stents	These devices are very small and have extremely small surface areas that would make branding very difficult, if not impossible. Marking methods tend to compromise device integrity.
GASTROENTEROLOGY DEVICES	
• Dilators • Feeding Tube Irrigation Adapters • Guidewires	These devices are physically too small. The geometry of the device does not afford ample space to fit the name/symbol of the manufacturer.
• T-Fasteners	These components are very small and have extremely small surface areas that would make branding very difficult, if not impossible.
GENERAL HOSPITAL AND PERSONAL USE DEVICES	
• Absorbent tipped applicators	These devices are physically too small to properly affix a label.
• Intravascular catheters • Stopcocks	These devices have very small surface areas that would make branding difficult, if not impossible, and may compromise the functionality of the devices.
• Intravascular administration sets and transfer sets	Marking methods may compromise the integrity, functionality or biocompatibility of the devices.
IN VITRO DIAGNOSTIC DEVICES	
• Analyte Specific Reagents	These devices are generally liquid products

	that are impossible to label due to their physical state. These products are contained in vials with labels affixed that identify the manufacturer.
• Blood Glucose Strips	Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices. These products are packaged in foil that identifies the manufacturer. The blood glucose strips are used in conjunction with a primary device (blood glucose meters) that identifies the manufacturer.
• Calibrators and Controls	These products are contained in vials with labels affixed that identify the manufacturer.
• In Vitro Diagnostic Test Systems	These systems contain liquid products that are impossible to label due to their physical state. Marking methods would compromise the integrity of biological products, such as antibody coated beads. These test systems consist of multiple components combined into a product kit with labels affixed that identify the manufacturer.
Surgical Devices	
• Clamps • Scalpels • Scissors • Stylets	These devices are very small and have extremely small surface areas that would make branding very difficult, if not impossible.
• Lancets	These devices are physically too small to properly affix a label.

Thank you for the opportunity to provide these comments. We recommend the Agency involve stakeholders in this process to better understand the large number of devices impacted, the steps needed to brand devices, and the financial implications. Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

April Veoukas

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Corporate Regulatory and Quality Science
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