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March 11, 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 (MDUFMA)***  
***Docket Number: 02N-0534***

Dear Sir/Madam:

In response to the Food and Drug Administration's (FDA's) request that stakeholders provide comments on specific provisions of MDUFMA, AdvaMed, the Advanced Medical Technology Association, is providing comments on section 301 of MDUFMA, which requires devices to bear their manufacturer's name, abbreviation, or symbol. AdvaMed represents more than 800 innovators and manufacturers of medical devices, diagnostic products, and medical information systems. Our members produce nearly 90 percent of the \$68 billion health care technology products consumed annually in the United States, and nearly 50 percent of \$159 billion purchased annually around the world.

AdvaMed's comments on section 301 of MDUFMA focus on the following areas:

1. Exemptions for certain medical devices
2. FDA's interpretation of the term "manufacturer"
3. Request for time extension and discussion of labeling costs

**1. Exemptions for Certain Medical Devices**

Section 301(a) of MDUFMA 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

02N-0534

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requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device.” AdvaMed’s understanding is that this provision is intended to ensure that end users are able to accurately identify the person placing the device into interstate commerce and taking responsibility for the device, particularly in those instances where a device has been reprocessed and placed onto the market by someone other than the original manufacturer.

AdvaMed and its members are concerned about the implications of section 301 because the application of labeling requirements to all devices may adversely affect consumers, the healthcare industry, and FDA. While the original intent of section 301 was to avoid confusion on the part of end users by providing information about the original manufacturer of the single use product that is subject to reprocessing, the language in the bill was broadened prior to enactment to include all device products, thus creating unforeseen difficulties for regulated persons and the agency. Most single use devices are never reprocessed and the cost to add the name of the manufacturer poses a significant burden to industry with little or no apparent benefit to the end-user or public health. Current labeling provisions at 21 CFR 801.1(a) require all devices to be conspicuously labeled with the name of the manufacturer or distributor. There is no evidence to suggest that these current labeling requirements are inadequate or that end-users are confused or unable to identify the person responsible for the device for single use devices that are not reprocessed. AdvaMed recommends that the agency interpret the provision as it was originally intended and that is to apply the requirements only to single use devices that are reprocessed.

AdvaMed believes that many of the devices manufactured by its member companies would qualify for a waiver of this provision for the reasons discussed herein. In many instances, medical devices are physically too small to carry the name, abbreviation, or symbol of the manufacturer. Many of the devices are 5x3 mm or smaller. Additionally, the geometry of some medical devices, such as small bone screws, does not afford sufficient space to fit the name, abbreviation or symbol of the manufacturer. More importantly, the placement of the name of a manufacturer may affect the safety and effectiveness of the device by imparting stress risers (surface discontinuities where imposed stress can be relieved) to the device. Due to the mechanical properties that some of these products must have in order to function in the body, the addition of stress risers may reduce their mechanical strength enough to compromise their effectiveness.

Additionally, the surface properties of some devices (e.g., small fabric covered devices, meshes, sponges, and nasal packing materials) may not allow for the legible printing of the manufacturer’s name, abbreviation, or symbol. Other devices (such as hemostatic agents, dental alloys and resins, surgical sealants or bone fillers) are supplied in a granular, powder, gel, cream or liquid form, and can not display the name of the manufacturer due to their physical state. Although the provision allows for the name, abbreviation or symbol of a manufacturer to be placed on attachments to the product, in

many cases, an attachment to a medical device may interfere with the use of the device, rendering the product unsafe or ineffective.

One example of a product category that AdvaMed supports a broad exemption for is permanent implants. 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. Due to the fact that these devices are not reused or reprocessed products, and the cost to label these products may pose an undue burden to industry, with little or no public health benefit. Therefore, a general exemption to the labeling provision should be granted by FDA for these product types.

In the case of *in vitro* diagnostics (IVD) devices, these products are not intended to be used 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. See 21 CFR § 809. Therefore, AdvaMed believes IVDs should be exempt from the provisions under section 301(a).

AdvaMed members have raised concerns that a literal application of section 301 to devices will result in the requirement of manufacturers to place their names on components or parts that are sold separately but are not finished devices. Specifically, AdvaMed urges FDA not to apply the requirements of section 301 to components or parts 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.

Moreover, FDA should exempt from the requirements of section 301 components and accessories that are packed and distributed in disposable, single use convenience kits. These kits typically contain, among many other things, products like gauze, surgical or examination gloves, alcohol wipes, and other consumable items that result in the kits being unfit and undesirable for reprocessing. As a result, the name of the person responsible for assembling and distributing the kit is always known to healthcare providers who use them. Because of labeling requirements under 21 CFR 801.1 and the fact that such kits are purchased by hospitals in large numbers from single suppliers, there is no likelihood that the “manufacturer“ of the kit will be unknown to the hospital or the person who uses the kit. Simply put, requiring manufacturer identification on the items in disposable convenience kits provides no consumer protection or protection to original manufacturers. It only creates costs, which could be considerable in light of the number of items in such kits and the nature of items like those just mentioned above and small implements like spatulas, toothpicks, tongue depressors, or wrenches. Marking each with a manufacturer’s name will unreasonably increase the cost of these lower cost items without benefit to public health.

AdvaMed believes that requiring each company to submit individual petitions for each medical device for which an exemption is requested will place an undue burden on the agency's resources. FDA could receive thousands of such requests. AdvaMed and its members recommend that FDA attempt to resolve this issue administratively through the development of a guidance document that does one of the following:

- 1) identify the types of devices that are exempt from the requirements of section 301. By including a list of exempt devices and thus providing the exemption through guidance, FDA will avoid the need to review individual petitions from numerous manufacturers for the same type of device; or
- 2) develop and identify definitive criteria for the types of products that would be exempt from section 301. Due to the rapid innovations of medical device technology, the types and number of products that may be exempted from these requirements would likely increase over time. By developing a definitive set of criteria for issuing exemptions, the agency allows for the future inclusion of new devices not currently marketed, while providing currently marketed products the opportunity for exemption.

However, if the agency determines that administrative implementation of section 301 cannot achieve a reasonable outcome to avoid over-regulation and empty costs, AdvaMed recommends that FDA seek to amend section 301 to limit its scope. By amending the provision, the agency can limit its applicability to specific devices. An amendment would provide end users the information they need to be properly informed when concerns or questions regarding a particular product arise. More importantly, an amendment also enables the agency to maintain the safety and public health while limiting undue burden placed upon industry.

To assist the agency in identifying types of devices that should be exempt from the requirements of section 301, AdvaMed has developed the following table of medical devices (Table 1.0) to illustrate the types of products that may qualify for exemption from the labeling provisions. The list of medical devices is not exhaustive and does not represent a complete list of the products that should be exempt from the provisions under section 301(a). The rationale for the exemption is also included. FDA may use this partial list to develop general rules for allowing exemptions for certain product types. Regulated industry hopes FDA can resolve this matter promptly, as it will become increasingly difficult for companies to comply with these labeling standards as the deadline approaches. To that end, AdvaMed would like to work with FDA to further develop this list or develop an approach through guidance that adequately captures a complete list of exempted devices.

**Table 1.0**

Type of Device	Rationale
<b>ANESTHESIOLOGY DEVICES</b>	
<ul style="list-style-type: none"> <li>• Anesthesia Breathing Circuits</li> </ul>	<p>The corrugated plastic comprising these devices is very difficult to imprint and may result in ineffective printing.</p>
<ul style="list-style-type: none"> <li>• Anesthesia Conduction Needles</li> </ul>	<p>These devices have very small surface areas that would make branding difficult, if not impossible. Marking methods may compromise the integrity, functionality or biocompatibility of the devices.</p>
<ul style="list-style-type: none"> <li>• Anesthetic Gas Masks</li> <li>• Oxygen Masks</li> </ul>	<p>The contoured surfaces of these devices make branding very difficult and costly.</p>
<b>BLOOD BANKING DEVICES</b>	
<ul style="list-style-type: none"> <li>• Hematype Segment Devices</li> </ul>	<p>These devices have very small surface areas that would make branding difficult, if not impossible, and may compromise the integrity, functionality or biocompatibility of the devices.</p>
<b>CARDIOVASCULAR/VASCULAR DEVICES</b>	
<ul style="list-style-type: none"> <li>• Adaptor Sleeves</li> <li>• Lead Caps</li> <li>• Lead Introducers</li> <li>• Lead Stabilizers</li> <li>• Parsonnet Pouches</li> <li>• Prosthetic Heart Valves</li> <li>• Topical Hemostasis Pads</li> </ul>	<p>Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.</p>
<ul style="list-style-type: none"> <li>• Vascular and non-vascular stents (including carotid, coronary, peripheral, neurovascular, and biliary)</li> <li>• Artificial Embolization Devices (e.g., Glue, PVA, coils)</li> <li>• Vena Cava Filters</li> </ul>	<p>These devices are very small and have extremely small surface areas that would make branding very difficult, if not impossible.</p>
<ul style="list-style-type: none"> <li>• Finishing Wires</li> <li>• Diagnostic Catheters</li> <li>• Guide Catheters</li> <li>• Guide Wires</li> <li>• Stylets</li> <li>• Vein Picks</li> </ul>	<p>Due to the physical size of the device, markings are unreadable without the aid of magnification.</p>
<ul style="list-style-type: none"> <li>• Repair Kit Sleeves</li> <li>• Seal and port plugs</li> </ul>	<p>Due to the physical size of the device, markings are unreadable without the aid of magnification and marking methods tend to compromise the integrity, functionality or biocompatibility of the device.</p>
<ul style="list-style-type: none"> <li>• Source Wires for Radiation Stent Systems</li> </ul>	<p>The Source Wire is a wire containing radiation that is integral with the Cartridge component of the Source Delivery Unit. It is not shipped</p>

Type of Device	Rationale
	separately. The Cartridge has labels affixed that identify the manufacturer.
<b>DENTAL AND ORTHODONIC DEVICES</b>	
<ul style="list-style-type: none"> <li>• Crowns, wires, brackets</li> </ul>	These devices are physically too small to be labeled. The geometry of the devices does not afford ample space to fit the name/symbol of the manufacturer.
<ul style="list-style-type: none"> <li>• Dental resins, alloys, cements</li> </ul>	Physical state of the device does not allow labeling.
<b>GASTROENTEROLOGY DEVICES</b>	
<ul style="list-style-type: none"> <li>• Feeding Tube Irrigation Adapters</li> </ul>	These devices are physically too small. The geometry of the device does not afford ample space to fit the name/symbol of the manufacturer.
<ul style="list-style-type: none"> <li>• Ostomy pouches and accessories</li> </ul>	Many of the ostomy accessories are physically too small and have extremely small surface areas. Additionally, ostomy bags are fragile products and labeling may compromise the integrity or the functionality of the device.
<ul style="list-style-type: none"> <li>• T-Fasteners</li> </ul>	These components are very small and have extremely small surface areas that would make branding very difficult, if not impossible.
<b>GENERAL HOSPITAL AND PERSONAL USE DEVICES</b>	
<ul style="list-style-type: none"> <li>• Lancets</li> </ul>	These devices are physically too small to properly affix a label.
<ul style="list-style-type: none"> <li>• Heparin Lock Injection Sites</li> <li>• Hypodermic Needles</li> <li>• Intravascular catheters</li> <li>• Stopcocks</li> <li>• Vial adaptors</li> </ul>	These devices have very small surface areas that would make branding difficult, if not impossible, and may compromise the functionality of the devices.
<ul style="list-style-type: none"> <li>• Bandages used for skin closure</li> <li>• Intravascular administration sets and transfer sets</li> </ul>	Marking methods may compromise the integrity, functionality or biocompatibility of the devices.
<ul style="list-style-type: none"> <li>• Elastic bandages, gauzes</li> </ul>	Marking may be illegible.
<b>GENERAL AND PERSONAL USE MONITORING DEVICES</b>	
<ul style="list-style-type: none"> <li>• Sterilization process indicator</li> </ul>	Nature of the device does not allow labeling.
<b>GENERAL AND PLASTIC SURGERY DEVICES</b>	
<ul style="list-style-type: none"> <li>• Absorbable and Nonabsorbable Surgical Sutures (poly(glycolide/L-lactide) stainless steel, poly(ethylene terphthalate), polypropylene, polyamide, silk, gut)</li> </ul>	These devices have very small surface areas that would make branding difficult, if not impossible, and may compromise the integrity, functionality, or biocompatibility of the devices.
<ul style="list-style-type: none"> <li>• Gauze, mesh, some drapes, some dressings</li> </ul>	Marking may be illegible and may compromise the integrity, functionality, and biocompatibility of

Type of Device	Rationale
	the devices.
<ul style="list-style-type: none"> <li>• Hydrogel would fillers</li> </ul>	The physical state of the products does not allow labeling on the device.
<ul style="list-style-type: none"> <li>• Removable staple and sutures</li> </ul>	These devices have very small surface areas that would make branding difficult, if not impossible, and may compromise the functionality of the device.
<b>IN VITRO DIAGNOSTIC DEVICES</b>	
<ul style="list-style-type: none"> <li>• Blood Glucose Strips</li> </ul>	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.
<ul style="list-style-type: none"> <li>• Calibrators and Controls</li> </ul>	These products are contained in vials with labels affixed that identify the manufacturer.
<ul style="list-style-type: none"> <li>• In Vitro Diagnostic Test Systems</li> </ul>	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.
<ul style="list-style-type: none"> <li>• Central nervous system fluid shunts and accessories</li> <li>• Needle electrodes</li> <li>• Neuro stimulation lead/lead extenders</li> </ul>	Due to the physical size of the devices, markings are unreadable without the aid of magnification and marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.
<ul style="list-style-type: none"> <li>• Burr hole covers</li> <li>• Resorbable or nonresorbable plugs, pins, soft tissue patches, and suture anchors</li> </ul>	Marking methods tend to compromise the integrity, functionality or biocompatibility of their devices.
<b>OPHTHALMIC DEVICES</b>	
<ul style="list-style-type: none"> <li>• Contact Lenses (Daily and Extended Wear)</li> <li>• Contact Lens Care Solutions</li> <li>• Ophthalmic Implants</li> <li>• Spectacle Lenses</li> </ul>	Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.
<b>ORTHOPEDIC/SPINAL DEVICES</b>	
<ul style="list-style-type: none"> <li>• Bone nuts, rods, screws, and tunnel plugs</li> </ul>	Due to the physical size of the devices, markings are unreadable without the aid of magnification and marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.

<b>Type of Device</b>	<b>Rationale</b>
<ul style="list-style-type: none"> <li>• Bone Void Fillers</li> </ul>	<p>These granule or injectable products would be impossible to label effectively due to their physical state.</p>
<ul style="list-style-type: none"> <li>• Bone Cement and Restrictors (resorbable or Poly(methyl methacrylate))</li> </ul>	<p>These powder and liquid products would be impossible to label effectively due to their physical state and marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.</p>
<ul style="list-style-type: none"> <li>• Cerclage Wires</li> <li>• Medical Stitching Needles</li> </ul>	<p>These components are very small and have extremely small surface areas that would make branding very difficult, if not impossible.</p>
<ul style="list-style-type: none"> <li>• Drill tip passing pins and small drills</li> <li>• Orthopedic guidewires</li> </ul>	<p>Due to the physical size of the device, markings are unreadable without the aid of magnification.</p>
<ul style="list-style-type: none"> <li>• Endo and Fixation Buttons</li> <li>• Polymer implants (elbow, finger, hip, knee, shoulder, toe and, wrist)</li> <li>• Suture anchors and washers</li> </ul>	<p>Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.</p>
<ul style="list-style-type: none"> <li>• Fixation fasteners, pins, screws, staples or wires</li> <li>• Single/multiple component metallic bone fixation appliances and accessories</li> <li>• Smooth or threaded metallic bone fixation fasteners</li> </ul>	<p>The devices are physically too small. The geometry of the devices, typically screwtype, does not afford ample space to fit the name/symbol of the manufacturer. The devices have a mechanical effect on the body; the addition of the name/symbol may impart stress risers to the device, which may reduce their mechanical strength and thus their effectiveness.</p>
<ul style="list-style-type: none"> <li>• Resorbable bone cement plugs, pins, soft tissue patches, and suture anchors</li> </ul>	<p>Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices and due to their resorbable nature, the manufacturers name would be lost during absorption.</p>
<ul style="list-style-type: none"> <li>• Wound Drainage Devices</li> </ul>	<p>Physically small in diameter, ineffective printing. These devices are used with foam products, which are incompatible with marking techniques.</p>
<b>SURGICAL HEMOSTATIC DEVICES</b>	
<ul style="list-style-type: none"> <li>• Collagen powders, sheets and sponges</li> <li>• Cellulose fibers, sheets, and mesh</li> </ul>	<p>These powder, sponge or sheet products would be impossible to label effectively due to their physical state.</p>
<ul style="list-style-type: none"> <li>• Gelatin powders, granules, and sponges combined with liquid thrombin</li> <li>• Hydrophilic and Hydrogel wound dressings</li> </ul>	<p>These gel-like resorbable devices would be impossible to label effectively due to their physical state.</p>
<b>SURGICAL SEALANT DEVICES</b>	



Type of Device	Rationale
<ul style="list-style-type: none"><li>• Polyethylene glycol (PEG) powders and associated buffers</li></ul>	These hydrogel resorbable devices would be impossible to label effectively due to their physical state.

**2. FDA's interpretation of the term "manufacturer"**

As amended by Section 301 of MDUFMA, a device will become misbranded under subsection 502(u) of the Food, Drug, and Cosmetic Act (FD&C Act or the Act) 18 months after MDUFMA's enactment unless the device, or an attachment to the device, bears the name, abbreviation or symbol of the manufacturer. For purposes of this provision, understanding what constitutes a "manufacturer" has become quite important because neither regulated persons nor regulators have settled on a conclusive interpretation that reflects Congress's intent. H.R. 3580 contained the identical language found in the enacted law for subsection 502(u). However, the legislative history is unrevealing on the meaning of the term manufacturer, except to the extent the term appears in Title III of MDUFMA, which "makes changes to the regulatory scheme for single use devices that are reprocessed." See H.R. Rep. No. 728, 107 Cong. 2d Sess. 44. The presence of this provision in Title III reflected the evolution of section 301 H.R. 3580 from one confined to single use device reprocessors to a more general one. However, AdvaMed contests that reason and Congress's stated purpose for the provision during negotiations should help define "manufacturer" as used in subsection 502(u).

Specifically, AdvaMed recommends that FDA define the term "manufacturer" broadly enough to reflect Congress's original intent to ensure that end users are able to accurately identify the person who placed a device into interstate commerce and took responsibility for it. The intent of the provision is to permit end users the ability to identify the person who made the device available for use, i.e., the reprocessor of a single use device, instead of the device's original manufacturer.

This approach is not unlike what FDA currently requires in its labeling regulations. When a company manufactures and distributes a device in its name, that name is required to appear on a device's label. 21 CFR § 801.1(b). However, in circumstances where the manufacturer is not responsible for distributing a device, the regulation does not require the manufacturer's name to appear on the label, but instead requires the name of the person taking responsibility for distributing the device. See 21 CFR § 801.1(c) (stating when a device bears the name of a person other than the manufacturer it must be "qualified by a phrase that reveals the connection such person as with such device; such as, 'Manufactured for \_\_\_\_', 'Distributed by \_\_\_\_', or any other wording that expresses the facts.")). For purposes of identifying for consumers the person responsible for a device, the regulation equates distributors with manufacturers. In effect, the FDA requires a name and address to be disclosed to consumers so that they will know how to contact the person responsible for placing a device into commercial distribution to, among other things, report problems with the device.

Although the term “manufacturer” is not defined by the Act, FDA’s regulations consistently demonstrate that the word is defined broadly to effect a public health purpose. Each definition is consistent with the notion that the person who takes responsibility for the device and offers it into commerce is a manufacturer for purposes of device regulation. For example, the MDR and Removal and Corrections Regulations, both include in the definition of “manufacturer” “persons who repackage or otherwise change the...labeling of a device in furtherance of the distribution of the device from the original place of manufacture.” 21 CFR §§ 803.3(o) and 806.3(g). Both regulations likewise identify persons who initiate specifications and distribute devices manufactured by another person as manufacturers. Even persons who only import devices into the country and distribute them are defined as “importers”, but under both regulations are regulated the same as, or very similar to, manufacturers. *See* 21 CFR §§ 803.40 and 803.42 (MDR reporting obligations of importers) and § 806.10 (importer and manufacturer removal and correction reporting obligations). In these instances, the public health is best protected by disclosing the person’s name that takes responsibility, in a sense credit, for distributing the device.

The registration regulations do not define manufacturer; they instead define the activities of manufacturing, preparing, propagating, compounding, processing or assembling devices. *See* § 807.3(d). Within this definition is the act of “repackaging or otherwise changing...labeling of any device package in furtherance of the distribution of the device from the original place of manufacture...;” also the regulation includes the mere importation of a device from a foreign manufacturer within this definition. *Id.* There is little question that FDA has not historically understood the word “manufacturer,” or the act of manufacturing, to be literally the person or process responsible for actually making devices. Indeed, the agency’s tracking regulation states:

*Manufacturer* means any person, including the importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in § 807.3(d) of this chapter.

21 CFR § 821.3(c) (emphasis in original). The device tracking regulation makes clear that the public health purposes of the Act supercede unduly narrow and literal understandings of terms like manufacturer. FDA must know who is accountable for the devices placed into interstate commerce. As a result, the term “manufacturer” must refer to the person who places their name on the device’s label and takes responsibility to further its distribution from the manufacturer to the consumer. To do otherwise would result in confusion among consumers. For example, to interpret “manufacturer” in subsection 502(u) to require that the name of the person who manufactures devices for a specification developer be placed on or attached to a device would be wholly inconsistent with FDA’s allocation of regulatory responsibilities for specification developers. Significantly, identifying the device by a manufacturing contractor whose name will not

appear in labeling would confuse consumers and not provide useful information about who to contact about device-related concerns. In the same regard, placing the name of the person who manufactures devices for a private label distributor on a device provides the consumer no useful information. Simply put, the name on or attached to the device should be consistent with the name that appears on the device label.

Furthermore, to ensure that complete adverse event information is provided to FDA it is critical that the name on or attached to a device match the name of the person who is identified in labeling as the person responsible for the device. In other words, there is little or no public health benefit to direct information from consumers to anyone other than the person who has a commercial connection with them. By understanding the term “manufacturer” in subsection 502(u) to mean the person who is identified in labeling and responsible for the device will ensure maximum adverse event reporting to the agency. In sum, consistent with the breadth FDA has applied to the words “manufacturer” and “manufacture” in its regulations, and to achieve subsection 502(u)’s purpose of informing users of the persons responsible for distributing devices. AdvaMed believes that FDA should interpret “manufacturer” broadly and avoid a narrow focus on the mere act of fabricating devices.

### **3. Request for Time Extension and Discussion of Labeling Costs**

As amended by Section 301 of MDUFMA, a device will become misbranded under subsection 502(u) of the Act 18 months after MDUFMA’s enactment unless the device, or an attachment to the device, bears the name, abbreviation, or recognized symbol of the manufacturer. After consulting with a substantial number of AdvaMed members, it is now apparent that the 18-month timeframe is simply impossible for manufacturers to comply with due to the complexities involved with implementation. Each device type needs to be assessed to determine the most cost-effective approach for adding the manufacturer’s name. Biocompatibility and functionality testing may be required to confirm that the addition of the name has no adverse effects on safety or performance specifications. For example, a company may need to conduct tests to ensure the safety of a dye that is used to label a product or determine if an etching technique renders a product unsafe. Companies will require more time to implement additional steps in the manufacturing process to ensure products are properly labeled. Additional time will also be needed to exhaust current inventory that is not branded with the manufacturer’s name. Thus, AdvaMed and its members request FDA to grant an extension on the current implementation deadline of April 2004. Manufacturers will need at least a 12-month extension beyond the current deadline to address the requirement for the many different device types that are affected.

At this time, AdvaMed believes the true cost estimates to be incurred by industry as a result of this provision are not fully known. In order to determine all relevant cost factors involved with the new labeling procedures, manufacturers will need to evaluate the application of new labeling requirements in their manufacturing process. Companies may

*March 11, 2003*

be required to purchase new labeling equipment in order to comply with the provision. The labeling process itself may incur substantial costs resulting from discards. Etching and other marking testing procedures may increase the number of discards a company may have. An increased number of discards could be devastating to smaller companies as it may decrease their product inventory and require additional resources to develop new product inventories. Additionally, companies will have to evaluate the feasibility and cost effects of adding a labeling procedure into its manufacturing process.

Another issue resulting from section 301 is that companies may not be able to exhaust their current inventories before this provision becomes effective. Manufacturers will have to determine if a product can be labeled post-production. If a device cannot be labeled after manufacturing, the products will have to be discarded. Inability to label post-production may also affect the ability of the manufacturer to provide the product through private distributors and kit manufacturers. Additionally, when products are returned, they are normally placed back into a company's inventory and would then have to be discarded if the product was returned after the provision's effective date. AdvaMed believes FDA should make it clear that the provision pertains only to medical devices manufactured after the effective date and not to devices made prior to the effective date. It would be extraordinarily burdensome on industry to rework existing inventory or discard existing inventory because they do not meet the labeling requirements.

AdvaMed appreciates the opportunity to provide these comments and would like to work with the agency to ensure the appropriate implementation of this key provision of MDUFMA.

Sincerely,



Janet Trunzo  
Vice President  
Technology and Regulatory Affairs