July 7, 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

In response to the Food and Drug Administration's (FDA's) request that stakeholders provide comments on specific provisions of MDUFMA, OSMA, the Orthopedic Surgical Manufacturer's Association is providing comments on section 301 of MDUFMA, specifically the provisions related to the determination that a medical device is misbranded unless it bears the name, abbreviation, or symbol of the manufacturer. OSMA represents more than **30** manufacturers of orthopedic devices.

OSMA'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 requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety or effectiveness of the device." OSMA'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. OSMA and its members are concerned about the implications of section 301 because the application of labeling requirements to all device,

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ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
An Association of Manufacturers Devoted to the Interest of the Surgical Patient
1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net

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 manufacturer of the product, 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. OSMA recommends that the agency interpret the provision as it was originally intended and that is to apply the requirements to single use devices that are reprocessed. OSMA 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 and 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, surgical sealants or bone fillers) are supplied in a granular, powder or liquid form, and cannot 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 OSMA 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, a general exemption to the labeling provision is requested.

OSMA members have raised concerns that a literal application of section 301 to devices will involve requiring manufacturer names on components or parts that are sold separately but themselves are not finished devices. Specifically, OSMA urges FDA not to apply the requirements of section 301 the

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
An Association of Manufacturers Devoted to the Interest of the Surgical Patient
1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net

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, healthcare providers who use them always know the name of the person responsible for assembling and distributing the kit. 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.

OSMA 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. OSMA 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.
2) Develop guidance that identifies 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

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1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net

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 resolutions are unfeasible or do not appropriately resolve this matter, OSMA recommends that FDA seek an amendment to MDUFMA that limits the application of the provision to single use devices that are reprocessed. An amendment to MDUFMA 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, OSMA has developed the following table of medical devices in the orthopedic area (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). While OSMA fully supports exclusion of all of the devices that were included in the ADVAMED comments for exclusion, we chose to focus our comments on the orthopedic arena only. 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. OSMA 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**
ORTHOPEDIC/SPINAL DEVICES	
• Bone nuts, rods, screws, and tunnel plugs	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.
• Bone Void Fillers	These granule or injectable products would be impossible to label effectively due to their physical state.
• Bone Cement and Restrictors	These powder and liquid products would be

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(resorbable or Poly(methyl methacrylate))	impossible to label effectively due to their physical state and marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.
• Cerclage Wires • Medical Stitching Needles	These components are very small and have extremely small surface areas that would make branding very difficult, if not impossible.
• Drill tip passing pins and small drills • Orthopedic guidewires	Due to the physical size of the device, markings are unreadable without the aid of magnification.
• Endo and Fixation Buttons • Polymer implants (elbow, finger, hip, knee, shoulder, toe and, wrist) • Suture anchors and washers	Marking methods tend to compromise the integrity, functionality or biocompatibility of the devices.
• Fixation fasteners, pins, screws, staples or wires • Single/multiple component metallic bone fixation appliances and accessories • Smooth or threaded metallic bone fixation fasteners	The devices are physically too small. The geometry of the devices, typically screw-type, 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.
• Resorbable bone cement plugs, pins, soft tissue patches, and suture anchors	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.
• Wound Drainage Devices	Physically small in diameter, ineffective printing. These devices are used with foam products, which are incompatible with marking techniques.

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SURGICAL HEMOSTATIC DEVICES	
• Collagen powders, sheets and sponges • Cellulose fibers, sheets, and mesh	This powder, sponge or sheet products would be impossible to label effectively due to their physical state.
• Gelatin powders, granules, and sponges combined with liquid thrombin	These gel-like resorbable devices would be impossible to label effectively due to their physical state.
SURGICAL SEALANT DEVICES	
• Polythylene glycol (PEG) powders and associated buffers	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.

Understanding what constitutes a "manufacturer" has become quite important because neither regulated persons nor regulators have conclusively interpreted a definition that necessarily reflects Congress's intent. H.R. 5651, the bill enacted into law, has no legislative history, except to the extent H.R. 3580, a predecessor bill, contains the same or similar language as the final law. 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, OSMA contests that reason and

Congress's stated purpose for the provision during negotiations should help define "manufacturer" as used in subsection 502(u).

Specifically, OSMA 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(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 affect 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,

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1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net

disclosing the person's name that takes responsibility, in a sense credit, for distributing the device, best protects the public health.

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 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 they use. 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 manufacturers 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.

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

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e-mail: rgames@bellsouth.net

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. OSMA 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. OSMA believes that these requirements should only apply to devices manufactured after the effective date. To require otherwise will result in significant waste and destruction of products.

In addition 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. Thus, OSMA and its members request FDA to grant an extension on the current implementation deadline of April 2004. Manufacturers will need at least a two-year extension to address the requirement for the many different device types that are affected.

At this time, OSMA 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 also be required to purchase new labeling equipment in order to comply with the provision. Additionally, companies will have to research 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

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
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1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net

inventories before this provision becomes effective. Extending the implementation date of this provision will limit some undue burdens and costs to industry.

OSMA 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,

William Christianson
President OSMA

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1962 Deep Valley Cove
Germantown, TN 38138 • Phone/Fax: 901-754-8097
e-mail: rgames@bellsouth.net