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BY HAND DELIVERY

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

RE: **Docket No. 01P-048**

Dear Sir or Madam:

On March 22, 2001, the Association of Disposable Device Manufacturers (ADDM) submitted a citizen petition requesting the Food and Drug Administration (FDA) to announce that failure to remove the trademark and other brand identification of the original equipment manufacturer (OEM) from a reprocessed single use device constitutes misbranding under section 502 of the Food, Drug, and Cosmetic Act (FDCA). The petition states that, because FDA characterizes reprocessing as the manufacture of a new device from raw material consisting of the used single use device, continued display of the OEM's name and trademark falsely labels the reprocessor's device as that of the OEM. The petition also provides additional reasons why it is misleading for reprocessed single use devices to bear the OEM's name and trademark.

On June 1, 2001, the Association of Medical Device Reprocessors (AMDR) submitted comments on ADDM's petition. AMDR states that FDA's characterization of single use device reprocessing is inaccurate: The used single use device is not raw material, but retains its identity as the OEM's device even after reprocessing. For that reason, according to AMDR, the reprocessed single use device is truthfully labeled as the

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OEM's product. In any event, AMDR asserts, device users know that falsely labeled single use devices are reprocessed because the users have arranged for the reprocessing to occur.

AMDR's comments do not address the issues raised in ADDM's petition because the comments reject the legal framework FDA has chosen for regulating reprocessed single use devices and ignore the fact that there are users of reprocessed single use devices other than hospital administrators and purchasing agents.

The following briefly elaborates on these points and comments on several specific statements in AMDR's comments.

1. According to AMDR, continued display of the OEM's name and trademark does not misbrand a reprocessed single use device. On the contrary, it would be misleading not to display them (AMDR comments at 5) because "[t]he reality . . . is that the users of reprocessed devices, i.e., physicians and hospitals, do not view reprocessing as a manufacturing function, but, rather, as a device cleaning, testing, and sterilizing service." (AMDR comments at 3.)

AMDR's argument entirely disregards FDA's legal framework for regulating single use device reprocessing. Whatever the reality may be from AMDR's perspective, the legal reality is that FDA characterizes single use device reprocessing not simply as "cleaning, testing, and sterilizing" a used single use device, but as taking a single use device that has been discarded and using it as raw material to manufacture a new device. In FDA's legal framework, the OEM's device ceases to exist as such. AMDR's position that the reprocessed single use device is the same device as the one designated by the OEM's name and trademark is therefore at odds with FDA's position that the reprocessed single use device is a different device.

2. Certainly, AMDR is correct that what its members actually do is prepare a used single use device for reuse. But if FDA regarded reprocessing as simply cleaning the OEM's discarded device and reintroducing it into commerce, the agency would also have to address the fact that the reprocessor is engaged in misbranding the OEM's device by reconditioning and marketing it contrary to the conditions of use in the OEM's labeling. By characterizing single use device reprocessing as the manufacture of a new device, FDA can, as an analytical matter, disregard the OEM's labeling on the theory that the original device has not been merely cleaned, tested, and sterilized, but has been used as raw material for a different device – that of the reprocessor.

FDA's theory may be debatable. Nevertheless, it is the theory the agency has chosen to apply – to the advantage of AMDR's members – and therefore the agency must

apply it consistently. Doing so means that, whatever AMDR believes "the reality" to be, in the legal framework FDA has, in fact, adopted, it is false to represent that the reprocessed single use device is the same as the OEM's device by continuing to display the OEM's name and trademark.

3. AMDR analogizes single use device reprocessing to the use of off-the-shelf components. AMDR says that FDA's enforcement policy treats single use devices as "raw materials/off-the shelf components of reprocessed finished devices." (AMDR comments at 3.) AMDR goes on to say that there is no FDA regulation or policy prohibiting the manufacturer's name and trademark to appear on off-the-shelf components when used in another manufacturer's device, citing the examples of a battery and a personal computer.

ADDM is not aware of any FDA statement that the agency views used single use devices as "off-the-shelf components." AMDR cites Melinda Plaisier's November 29, 2000, letter. (AMDR comments at 3 n.7.) The letter refers to a reprocessed device as a device "from a raw material that was a previously-used, single use device . . . ." It does not refer to a single use device – original or used – as an "off-the-shelf component."

"Off-the-shelf component" is not a defined term. The examples AMDR gives are of finished products, not raw materials. A finished product used as a device component is incorporated as such into a device in a way that is consistent with the manufacturer's intended use for the finished product. Thus, a battery is incorporated into a powered device as a battery, and the maker of the battery intends that it be used to provide electrical power. In this context, the continued display of the battery maker's trademark, e.g., "Delco," is, at least as to the battery, truthful and not misleading: The battery in a powered device is the same battery the manufacturer that owns the trademark sells as a finished product; the battery is used as the manufacturer intended it to be used.[1]

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[1] There are limits to displaying a component-maker's trademark. For example, it would not be acceptable to display the trademark on a component of a device so prominently that the buyer of the device would be misled as to the identity of the manufacturer of the device itself. Therefore, even accepting AMDR's premise, a reprocessed single use device would be misbranded by the OEM's trademark. A device buyer does not conclude that Delco makes a powered device that uses a Delco battery, because the buyer knows that the battery is a component. But the buyer of a reprocessed single use device does not know that the OEM's single use device is, in its entirety, a "component" of the reprocessor's device, and will therefore erroneously conclude that the reprocessed device is made by the company whose trademark it still displays.

AMDR's analogy to a finished product used as an "off-the-shelf component" does not fit single use device reprocessing. As a finished product, the OEM's single use device is not intended to be, or to become, a "component" of another company's reprocessed version of the identical device. It is intended to be used as a single use device and discarded. Nor is the OEM's single use device incorporated as a finished product into the reprocessor's device. Instead, the used, discarded single use device becomes available to the reprocessor as medical waste that serves as raw material to manufacture a new device.

AMDR is therefore wrong in analogizing used single use devices to off-the-shelf components, and in suggesting that FDA itself would so classify them. In fact, FDA's only characterization of discarded single use devices is as "raw material." The OEM's name and trademark are not used by the OEM to signify that a single use device is raw material for reprocessing. They are used to signify that a single use device is a finished product to be used as a medical device, and then disposed of. The "raw material" the single use device becomes at that point is not the product the OEM's name and trademark stand for. Therefore, for a reprocessor to continue to display them falsely labels the reprocessor's product as that of the OEM.

As to brand names or trademarks on raw material used to manufacture devices, AMDR cites no examples. It may be that there are instances in which the source of a raw material (such as the manufacturer of a polymer) used to make a finished device is identified on the device product or in its labeling. If that occurs, however, the name or trademark will be one associated with a substance intended to be used as raw material, i.e., to undergo further processing, and the name or trademark will appear on the device or in its labeling in a way that makes clear that it refers to a raw material, not to the device itself. OEMs do not intend their names, or the trademarks for their single use devices, to denote products to be used as raw material for further processing. Even if they did, displaying the OEM's name and trademark as in the examples attached to ADDM's petition would hardly make clear that the product denoted by the OEM's name and trademark is "raw material" rather than the device itself.

4. AMDR argues that misuse of OEM names and trademarks does not cause misbranding because hospitals, some physicians, and the reprocessors themselves are aware that the single use device has been reprocessed. (AMDR comments at 4-5.)

There is no exemption from the FDCA's prohibition of device misbranding for situations where the sellers and buyers of a device know that the device bears labeling with false claims. FDA is a law enforcement agency. Unlike a court in a Lanham Act case, FDA does not determine whether buyers of products subject to the FDCA are able to avoid being misled by a misbranded product through the exercise of special efforts or

the happenstance of personal knowledge. Instead, FDA examines the labeling of a device, and determines whether the labeling is false or misleading. If it is, the product is misbranded.

In the case of reprocessed single use devices, FDA has characterized the reprocessor's product as a new device and the used single use device as raw material. In FDA's own view, therefore, continued use of the OEM's trademark misbrands the single use device, whether or not hospitals know that the single use device has been reprocessed.

Moreover, AMDR's assumption that no one is misled by false references to the OEM's name or trademark is both unsubstantiated and paternalistic. Hospital employees and committee members are obviously knowledgeable about the details of a single use device reprocessing initiative those employees and committee members have reviewed and endorsed. However, the reprocessed single use devices will not be used by them. They will be used by the hospital's staff physicians or physicians with admitting privileges. Some of these physicians may be aware of what the hospital has decided or even have participated in the decision. But neither AMDR nor FDA has any practical means for assuring that all treating physicians will know what the hospital knows. One thing is certain, however. They will all see the OEM's trademark if it remains on the reprocessed device.

The FDCA guards against physicians being misled by device labeling. It does so by requiring the labeling for device products to be truthful and accurate. FDA cannot dispense with this statutory safeguard in any circumstance, much less one where a device bears false labeling and the only source of information about the true nature and origin of the product are internal hospital documents or individual hospital employees.

Not only is AMDR's position factually unsupported, it is also paternalistic. The hospitals, according to AMDR, can be trusted to exercise due care in selecting single use devices for reprocessing and in choosing qualified reprocessors. It is therefore "simply absurd" to suggest that users of reprocessed devices could be misled by the presence of the OEM's trademark. (AMDR comments at 4.) AMDR's comments make clear that by "users," AMDR means hospital employees, along with some hospital physicians in their capacity as technical advisors to the hospital. But the true users of reprocessed single use devices are all of the treating physicians, and their patients, who practice at the hospital where reprocessed single use devices are made available. These users should not be required to rely on the judgment of the hospital staff as a surrogate for accurate knowledge about the nature of a medical device to be used in treatment.

There is no justification for depriving practicing physicians of accurate device labeling so that they, along with hospital management, have the opportunity to exercise informed judgment. A reprocessed single use device with the OEM's name and trademark provides physicians with information that is false. At a minimum, this false information raises an obstacle to the exercise of informed judgment by physicians, and, at worst, it prevents the exercise of any judgment at all.

5. AMDR states that section 502(b) of the FDCA, in 21 C.F.R. § 801.1(c), are not violated when the label or labeling of the reprocessor's product bears the identity of the OEM. (AMDR comments at 5.) AMDR's position is based on the fact that section 502(b) of the FDCA and section 801.1 of FDA's regulations do not explicitly prohibit labeling a device with the name of a company that is not its "manufacturer, packer, or distributor."

This misses the point. If the statute and regulation require "the manufacturer" to be identified on the label of the device, and if the device label identifies an entity other than "the manufacturer" along with the entity that is "the manufacturer," then the label has failed to identify "the manufacturer." Instead, it has provided ambiguous information from which the user of the device cannot draw a reliable inference. Such a label violates section 502(b) and section 801.1.

AMDR recites the provisions of section 801.1 to demonstrate that none of them explicitly prohibits the use on a device label of the name of a company that has no relationship to the labeled product. However, when section 801.1 was drafted, it may not have occurred to FDA that the regulations needed to address the unlikely belief that such a practice would be acceptable. It is not acceptable to identify uninvolved companies on device labels if doing so misleads users of devices into concluding that such companies have something to do with the product on whose label their names appear. Such a conclusion is inevitable, because there is no good reason to name a company on a label if it is not involved in making or selling the device.

Whether or not section 801.1 specifically forbids it, therefore, identifying uninvolved companies on device labels violates sections 502(a) and 502(b). The parallel drug label regulation, § 201.1, was amended 20 years ago to prohibit explicitly the presence of extraneous company names on drug labels, because of events that occurred in the drug industry after the original regulation was issued. The legal basis for the amendment was that including extraneous company names on drug labels was misleading. Even though the device regulation was not amended at that time, it is nevertheless the case that using extraneous company names on labels is as misleading for devices as it is for drugs.

AMDR argues that leaving the OEM's name on the single use device or its label, or identifying the OEM in the label of the reprocessed single use device, are acceptable based on an analogy to "servicers and refurbishers" of capital equipment. (AMDR comments at 8.) This analogy is no more apt than equating the discarded single use device with a finished "off-the-shelf" component. A device that is capital equipment, such as an imaging machine, is a multiple-use device whose manufacturer intends it to be serviced periodically or as needed. Although the manufacturer may establish a service life for such a device as a recommendation and for warranty purposes, the refurbishing of the device is not inconsistent with the manufacturer's labeling, and the device itself is not considered by FDA to be raw material for a new device.

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ADDM's petition requests that, consistent with the legal framework it has adopted, FDA enforce the rules that apply to reprocessed single use devices considered as new devices made from raw material consisting of discarded single use devices. Those rules include not misrepresenting the identity of the reprocessed device or its manufacturer through the continued display of the OEM's name and trademark.

AMDR's comments do not address the issues raised by ADDM. Instead, AMDR repudiates FDA's legal framework and insists that the use of the OEM's name and trademark is proper because a reprocessed single use device is not a new device, but the OEM's original device. AMDR also argues that misbranding a reprocessed single use device by identifying it with the OEM's name and trademark is harmless because some people in hospitals are aware that reprocessed single use devices are used.

By its unwillingness to discuss the misbranding issues in the context of the legal structure FDA itself has put in place, by its resort to false analogies, by its emphasis on common knowledge as an antidote to false labels, and by inviting FDA to consider the possible economic motives of ADDM's members rather than the merits of the petition, AMDR only highlights the legal indefensibility of the practices from which ADDM's petition seeks relief.

Respectfully submitted,

Thomas Scarlett

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