

**ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS**

*Providing industry views on single patient use medical devices*

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March 20, 2002

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

**Re: Docket No. 01D-0514; Guidance on Labeling of Reprocessed Single Use Devices**

Dear Sir or Madam:

The Association of Disposable Device Manufacturers (ADDM) respectfully submits these comments to the Food and Drug Administration's (FDA's) December 20, 2001 Federal Register notice regarding the contents of a proposed guidance document on the labeling of reprocessed single use devices with respect to the names of the original equipment manufacturer (OEM) and the reprocessor.

On March 22, 2001, ADDM submitted a citizen petition (the Petition) requesting that FDA recognize as misbranded under Section 502 of the Federal Food, Drug, and Cosmetic Act (FDC Act) any reprocessed single use device bearing an OEM trademark or referencing the OEM in its label (Attachment A). The legal grounds for this request were fully articulated in the Petition and are incorporated here by reference. ADDM continues to believe that references to the OEM or its product on a reprocessed single use device or its label render the reprocessed device misbranded.

In its response to the Petition, FDA recognized that the existence of OEM names and trademarks on reprocessed single use devices may be misleading. The agency, however, noted its belief that such implications could be remedied by disclosure of additional information. ADDM disagrees.

The very foundation of FDA's acceptance of reprocessed single use devices as consistent with the FDC Act is FDA's determination that the reprocessor manufactures a distinct new device – a device for which the OEM is neither a manufacturer nor even a willing raw material supplier. If it has any relationship to the reprocessed device, the OEM is, at best, an objecting observer. Section 502 of the FDC Act does not tolerate the sale of a medical device emblazoned with the name of a manufacturer so unrelated to its creation and irresponsible for its performance. For FDA to find otherwise for reprocessed single use devices, while adhering to the equity tenets of the Administrative Procedure Act, requires a willingness to find, for instance, that a relatively unknown OEM (Company A)

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that purchases polymer pellets from a well-respected OEM (Company B) could emblazon Company B's name on its devices. This result is unacceptable. No amount of additional information contemplated in the proposed FDA guidance could cure the misbranding.

That FDA is prepared to exempt reproprocessors from enforcement action for this type of misbranding may be related, in part, to the obstacles associated with reproprocessor compliance. With respect to the OEM name and marks, reproprocessors of single use devices are faced with one of three situations when manufacturing (that is, reprocessing) their devices: (1) no OEM marks appear on the device, (2) OEM marks on the device can be easily removed, covered or obliterated, or (3) OEM marks on the device are lasting and their removal would require additional manufacturing to restore some level of device integrity. Notwithstanding these three possibilities, FDA's resolution of this issue must be independent of the ease with which OEM marks can be removed. Devices are no less misbranded under the FDC Act because making them not misleading is difficult. Reprocessors have voluntarily chosen to manufacture products regulated under the FDC Act and must be required to comply with all sections of that act, including Section 502.

FDA's denial of the Petition disregards the potential of the OEM marks to mislead except as it relates to MDR reporting. More important than adverse event reporting, however, is the prevention of the adverse events themselves. OEM marks on a reprocessed device may prevent a treating physician from selecting a never before used device when that is what is indicated for his patient.

ADDM believes that reprocessed single use devices must bear no unauthorized reference to the OEM. In light of FDA's position that the misleading nature of the OEM marks can be remedied by providing additional information, however, ADDM has considered what minimum information would assist the user in understanding the misleading use of the OEM marks. First, the name of the reproprocessor would have to be placed on the device itself in a manner at least as prominent and at least as permanent as the name of any OEM or the OEM's device. As noted in the Petition, ADDM also believes that the device and its label must note that the OEM has not determined that the device is fit for reprocessing.<sup>1</sup> The Petition lists additional material facts which ADDM believes must

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<sup>1</sup> In its response to the Petition, FDA disagrees with ADDM's position that this information is material because the OEM's determination is not a prerequisite to reprocessed device clearance. ADDM agrees that this information would not be required for a reprocessed device that bore no mention of the OEM. However, when the OEM name or mark is on the device, this information is necessary to rebut the presumption that the OEM stands behind the current use of the device.

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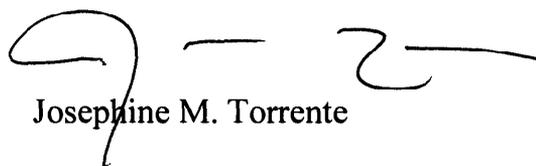
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be disclosed in the reprocessed device's labeling in order to diminish the misbranding caused by use of the OEM name.

In keeping with its mission to protect the public health, FDA must assure that physicians and other device users are not misled into believing they are using one device when, in fact, they are using another. ADDM looks forward to swift resolution of this issue.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized initial 'J' followed by a horizontal line and a flourish that ends in a hook.

Josephine M. Torrente

JMT/dmh  
Enclosure