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September 22, 2003

Food and Drug Administration
Division of Dockets Management (HFZ-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

1930 '03 SEP 23 A9:11

SUBJECT: Medical Device User Fee Modernization Act (MDUFMA)
Section 301: Identification of Manufacturer Labeling Requirement
Docket No. 03D-0226

We welcome the opportunity to comment on this Draft Guidance.

MDUFMA Section 301(a) provides that a device would be deemed misbranded:

> 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.

As MDUFMA stands, requiring the name of the manufacturer to appear on each device will adversely our competitive position as an importer and distributor of a variety of medical devices. These requirements will significantly increase our costs by requiring new labeling for all of our products on the devices themselves, unless the requirement is specifically waived.

- For example, consider the implications of labeling each patient exam glove, gauze pad with the name of the manufacturer.
- At a time of budgetary constraints, the cost related to enforcement of Section 301 would be prohibitive.
- The additional costs of labeling all medical devices may exceed the cost of the devices themselves.

This action also jeopardizes the viability of our contract customers branded and private label strategies.

- Private labeling and contract manufacturing are widely recognized tools for keeping consumer costs low.
- We also have a very reliable method of traceability with our lot numbering system.

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In order to address these issues, we concur with the HIDA proposals that FDA consider the following:

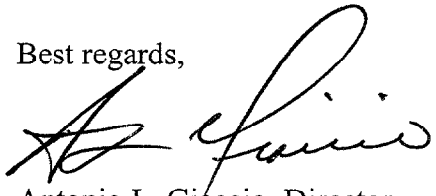
a. Adopting the position that the new labeling requirement of Section 301 should be applied only to reprocessed medical devices, but waived as not feasible for all other medical devices.

b. For all other medical devices, continuing to enforce the definition of manufacturer as interpreted in 21 C.F.R. § 807.3 (d) and 21 C.F.R. § 801.1(c), as these requirements are believed adequate to ensure the proper identification of a responsible party for the consumer. (In many cases, these current regulations provide the name of a domestic contact for the consumer, whereas Section 301 could force the consumer to attempt to locate a contract manufacturer outside the United States.)

c. If necessary, in order to clarify the applicability of Section 301 in accordance with Paragraph a above, (i) seeking an amendment to Section 301 that makes clear that the new labeling requirement applies only to reprocessed devices, and (ii) in the interim, issuing a guidance indicating that FDA will continue to exercise enforcement discretion until the law is amended.

We appreciate this opportunity to comment on the Draft Guidance and strongly urge the FDA to reevaluate the underlying law to take into consideration how this section would impose tremendous regulatory burdens on Industry and dramatically increase costs for consumers.

Best regards,



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