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OFFICE OF THE EXECUTIVE DIRECTOR
JOHN ELDRED

September 24, 2003

Dr. David W. Feigal, Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT: Medical Device User Fee Modernization Act (MDUFMA)
Section 301: Identification of Manufacturer Labeling Requirement

Dear Dr. Feigal:

On behalf of the Dental Trade Alliance (DTA), formerly the Dental Manufacturers of America, Inc., I am submitting these comments regarding MDUFMA Section 301 Draft Guidance. These comments further define and amplify similar concerns raised by and/or discussed with the American Dental Trade Association (ADTA), regarding MDUFMA.

MDUFMA Section 301(a) provides that a device will 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 affect both consumers and the healthcare industry. The requirements of Section 301 will increase healthcare costs and imposes significant burdens in the manufacturer and consumer communities by:

1. requiring new labeling for <u>all</u> products on the devices themselves, unless the requirement is specifically waived.

   - Please consider the implications of labeling each glove, tongue blade and gauze pad with the name of the manufacturer.
   - Any list of specific waivers for simple disposable devices will be quite long and may be very difficult to administer, **and waste a great deal of time and resources in industry and government.**.
   - We believe that the cost related to enforcement of Section 301 will easily exceed $100,000,000 and that the legislation will impact over 12,000 firms.

- The additional costs of labeling all medical devices (some devices have never before, to the best of our knowledge and belief, been labeled, e.g. exodontia sponges) may in some cases exceed the actual cost of the device.
- Examples of costs relating to tens of thousands of products:
  - Devising the new texts required by Section 301 and reconciling these with existing labeling and any contractual agreements.
  - Conceptualization of and planning for labeling processes
  - Fabricating the equipment for labeling
  - Restructuring facilities to accommodate additional equipment.
  - Documenting and validating the labeling processes for each medical device
  - Proving the stability of such labeling in processing, sterilization and use
  - Insuring that such labeling does not adversely impact the safety and effectiveness of any device
  - Actual labels and labeling materials, inspection, documentation, and related rejections required to control the quality of such new labeling

2. introducing more chemicals and dyes into the environment and diminishing the productivity of manufacturers without commensurate social benefit.
   - This is contrary to public policy.

3. negatively affecting the competitive structure of the U.S. medical device industry.
   - The U.S. medical device industry is one of the few with a positive trade balance.

4. jeopardizing the viability of many contract manufacturers and the production strategies of many manufacturers' branded and private label companies.

5. reducing the possibilities for, and the value of, private labeling by distributors and contract manufacturing by branded manufacturing companies.
   - Private labeling and contract manufacturing are widely recognized tools for keeping consumer costs low.

6. adversely affecting consumer brand confidence in existing products.

7. confounding USFDA efforts toward "international regulatory harmonization".

In order to address these issues, HIDA proposes that FDA consider the following:

a. Adopting the position that the new labeling requirement of Section 301 should be applied only to reprocessed, **single use** 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 **and deal with** a contract manufacturer outside the United States.)

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,

John Eldred

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cc: DMA Officers
Mr. Napoleon Monroe
Dr. H. Neal Dunning

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