DENTAL MANUFACTURERS OF AMERICA, INC.
FOUNDED 1932

123 South Broad Street • Suite 2030 • Philadelphia PA 19109-1020
(215) 731-9975 • Fax (215) 731-9984
www.dmanews.org • e-mail: staff@dmanews.org

OFFICE OF THE EXECUTIVE DIRECTOR
JOHN ELDRED

February 10, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NUMBER 02N-0534

TO WHOM IT MAY CONCERN

We have received the notice entitled "Medical Device User Fee and Modernization Act of 2002, Establishment of a Public Docket, 2/4/03, Docket Number 02N-0534."

In response to your request for written comments, please find attached our letter to Dr. David Feigal, which provides the reader with the position of the Dental Manufacturers of America, Inc. relative to MDUFMA.

Thank you for the opportunity to provide comments.

Yours very sincerely,

John Eldred (Kal)

John Eldred
Executive Director

JE/mfa
Enclosure

02N-0534

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OFFICE OF THE EXECUTIVE DIRECTOR
JOHN ELDRED

January 7, 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

Dear Dr. Feigal:

The Dental Manufacturers of America (DMA) based in Philadelphia, Pa., represents over 200 firms that manufacture, distribute, repackage, relabel or engage in other aspects of the US dental device industry. Our members range from the largest to the smallest of these members of the medical device industry; we have worked cooperatively with your Center to achieve close cooperation and compliance with the medical device regulations. The passage of the Medical Device User Fee and Modernization Act, however, did not allow for input from DMA and many other associations representing various aspects of the medical device industry. Our members are particularly concerned that Section 301. "Identification of Manufacturer of Medical Devices" may have disastrous results for many of our members, many other medical device firms, and on the competitive posture of the U.S. medical device industry if it is strictly interpreted. We refer to Section 301, (a), (u): "If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the **manufacturer** [emphasis added] 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."

This law is rendered unintentionally vague because of the myriad of meanings of the term **"manufacturer"** at various places in the medical device amendments. For example the Quality Systems Regulation (Section 820) has different uses of the term than do the Registration and Listing regulations (Part 807) and these are still different than Section 801 "Labeling." We believe that this law may have intended that the "person" responsible for the device in the US be listed on the device. This view has been strengthened by discussions between experts at Advamed and DMA's Regulatory Affairs Consultant, Dr. H. Neal Dunning. This would be eminently reasonable since it would help point out the proper firm to file adverse event reports, applications for premarket clearance, and other essential trade and regulatory operations. We would point out, however, that the person responsible for a device may be (as listed in 807.3 (d)) the (1) repackager/relabeler, (2) initial distributor of an imported device or (3) specifications developer, as well as the manufacturer. Further, a common (and useful) way of showing who is responsible for a device is that described in 801.1 (c). Therefore, a strict interpretation of Section 301 would seem to require the rewriting of the several regulations cited above.

We wish to stress that strict interpretation of Section 301 could negatively impact the competitive posture of the medical device industry. We realize that there is an 18 month delay in this section. However, this is very brief if one considers the time required to prepare a thoughtful guidance document and the lead period that responsible firms would need in order to redesign their labeling and, indeed, their business practices.

Therefore, we urgently request that you initiate the preparation of a guidance document to avoid the severely adverse effects of this section (Section 301) immediately. We note that this section provides flexibility to "The Secretary" in waiving the requirements of this section. However, this appears to be device specific. If so it would provide only a partial solution. A general waiver, allowing labeling consistent with 801.1(c), would be one very logical solution to the quandary in which several of our members find themselves.

Your prompt consideration will be sincerely appreciated.

Very truly yours,

John Eldred
Executive Director

cc: DMA Officers/Directors
DMA Regulatory/Technology Committee
Dr. H. Neal Dunning, DMA Regulatory Affair Consultant
Dr. Mark McClellan, FDA Commissioner
Dan Troy, Esq., FDA General Counsel
Ms. Janet Trunzo, Advamed