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OFFICE OF THE EXECUTIVE DIRECTOR
JOHN ELDRED

April 7, 2003

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

RE: DOCKET NUMBER 02N-0534: Medical Device User Fee and Modernization Act of 2002 (MDUFMA), with special reference to Section 301—Identification of Manufacturer.

Dear Sir/Madam:

We wish to follow-up our earlier comments, addressed to Dr. David Feigal and to this docket, on MDUFMA of Feb. 10, 2003.

We note that some major trade organizations and firms have now commented on the **unexpected** and highly negative effects that would accompany strict interpretation of the term "manufacturer" in Section 301. As stated earlier, we wish to encourage prompt development of a guidance document that will interpret the term "manufacturer" to include the myriad uses it has in current FDA regulations regarding labeling (Part 801); adverse event reporting (Part 803); establishment registration and device listing (Part 807); and quality systems (part 820). The important point is that the term "manufacturer" be interpreted as the firm that is **responsible** for the device in the US market and that would respond to consumers and compliance requirements of the device. It appears that if this is not done, a large number of regulations will have to be rewritten and common industrial practices changed accordingly with no discernible benefit but with disastrous effects on the United States medical device industry and the balance of trade in one of the few areas dominated by domestic firms.

It is noted that the other sections of TITLE **III—ADDITIONAL AMENDMENTS**, namely Section 302 and 303, **deal only with reprocessed single-use devices.** We believe that the speed with which MDUFMA became law, motivated by industry's wish to prevent improper re-use of single-use devices, and FDA's wish to obtain user fees, Section 301 was inadvertently applied to all medical devices when it was really intended to apply **only** to reprocessed single-use devices. Therefore, as alternatives to our earlier suggestion (reiterated above) we would recommend that the guidance document state something to the effect that "Section 301 is **interpreted** to apply only to reprocessed devices that were originally manufactured as single-use (disposable) devices." If this kind of interpretation is not within FDA's authority, we would request that Section 301 be stayed until the results of its implementation on the financial viability, safety, and effectiveness of medical devices involved can be determined.

We wish to thank you for this opportunity to comment on MDUFMA and appreciate your prompt consideration.

Sincerely,

John Eldred
Executive Director

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