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April 1, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm., 1061
Rockville, Maryland 20852

Re: (Docket #02N-0534) "Medical Device User Fee and Modernization Act of 2002"

Dear Sir or Madam:

Cardinal Health, Medical Products and Services (Cardinal) appreciates the opportunity to comment on the "Medical Device User Fee and Modernization Act of 2002" (MDUFMA).

1.

TITLE III – ADDITONAL AMENDMENTS

Sec. 301 IDENTIFICATION OF MANUFACTURER OF MEDICAL DEVICES.

(a) In General. – Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(u) If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer or a unique and 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.".

(b) Effective Date. – The amendment made by subsection (a) takes effect 18 months after the date of the enactment of this Act, and only applies to devices introduced or delivered for introduction into interstate commerce after such effective date.

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02N-0534

Comment:

Cardinal respectfully requests that FDA exercise its enforcement discretion and stay the enforcement of this provision of MDUFMA. Obligating the manufacturers of medical devices to put their name, name abbreviation or symbol on every device or device attachment will not contribute, in a significant way, to the safe and efficacious use of the device in question. On the contrary, this obligation will contribute to ambiguously labeled product, numerous petitions made to FDA by manufacturers requesting exemption, and potentially an inadequate supply of product in the short term.

We believe that ambiguously labeled product will result from the implementation of this obligation since many of today's device manufacturers will have to put their names on product that is made by injection molding. This manufacturing process will make it difficult to remove the manufacturer's name, if such a product is reprocessed or if the reprocessor doesn't remove the original manufacturer's name, the continued sale of a product that bears at best multiple names. A scenario could even exist in which a reprocessed device has the name of one manufacture on the product itself and that of a completely different manufacturer, i.e., reprocessor on the additional labeling.

Procedure Kits present another example of the ambiguous situations that will arise. Such Kits are considered to be medical devices due to the further processing assembled components (devices) undergo. FDA considers Kit manufacturers to be device manufacturers with all associated responsibilities. These responsibilities could conceivably include the obligation to apply the Kit manufacturer's name not only to the outer labeling of the Kit but also to the included components (devices) of the Kit. Since these devices would have already been "branded" by their manufacturers, you can imagine the confusion or difficulty that would be created.

In today's world of medical device supply, many products are made by contract manufacturers. Such manufacturers would have to possess specific manufacturing equipment (molds) with the name of the correct manufacturer on them. Additionally, if a manufacturer supplied his product to various distributors in a Private Labeled scenario each product would have to be identified in a "distributed by" fashion, further complicating the matter.

Many of today's medical devices are so small that the addition of a name on the product itself would be impossible or in the case of permanently implanted devices, needless. Without doubt the manufacturers of such products would petition FDA for an exemption from the obligation, further straining FDA's limited resources.

Finally, realistically speaking, with only a year left before the effective date of the obligation, many manufacturers will not be able to obtain new injection molds or other sources of supply, i.e., contract manufacturers or Private Label suppliers able to provide product compliant with the new obligations.

2.

Sec. 738 AUTHORITY TO ASSESS AND USE DEVICE FEES.

(g) CONDITIONS. –

"(g)(1)(A)(ii)(II) - The Comptroller General of the United States shall submit to the Congress a report describing whether and to what extent the Secretary is meeting the performance goals identified for such fiscal year, and whether the Secretary will be able to meet all performance goals identified for fiscal year 2005. A report under the preceding sentence shall be submitted to the Congress not later than July 1 of the fiscal year with which the report is concerned."

Comment:

It is our understanding that within the body of the above mandated letter "performance goals" must be identified to the Congress. All of the "performance goals" that we have seen published to date concerning Premarket Notifications are related to the "Traditional" type of Premarket Notification submission.

Cardinal believes that it would be beneficial to identify performance goals separately for the "Abbreviated" type of Premarket Notification submission. Hopefully, such identified performance goals would identify goals relating to a threshold shorter than the 90 day threshold used for "Traditional" submissions due to the anticipated shorter review time of an "Abbreviated" submission.

We also believe that it would be beneficial to codify the Food and Drug Administration's commitment to complete the review of the "Special" type of Premarket Notification submission within 30 days. Including this commitment within the FDA's letter to the Congress would accomplish this since the Congressional letter is to be published in the Federal Register.

Please feel free to contact me at 847-785-3310, if there are any questions concerning our comments or if clarification is required.

Sincerely,

Joseph A. Mertis

Joseph A. Mertis
Director, Regulatory Affairs