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MassMEDIC
Massachusetts Medical Device Industry Council

An industry
association for innovation
and economic growth
in Massachusetts

May 1, 2003

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

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

Dear Sir/Madam:

The Massachusetts Medical Device Industry Council (MassMEDIC) is pleased to present additional comments relative to the implementation of the Medical Device User Fee and Modernization Act (MDUFMA) as it relates to the Center for Biologics Evaluation Research (CBER).

MassMEDIC is an association of 285 member organizations - medical device and diagnostic manufacturers, suppliers, research institutions and academic health centers - that promotes the unique interests of one of the nation's most significant clusters of medical technology development. Since its establishment in 1996, MassMEDIC has taken a prominent role in supporting federal policies that expedite the delivery of medical technologies to patients and healthcare providers. MassMEDIC actively supported passage of the Food and Drug Modernization Act of 1997 and MDUFMA, enacted last year.

MDUFMA Implementation and CBER

Among its members, MassMEDIC represents manufacturers of medical devices that are used in surgical and blood bank applications and have had experience with both CRDH and CBER for review of 510(k) submissions. These two centers have a very different approach to device reviews, and this is particularly true with respect to devices that are reviewed by the Division of Hematology within CBER.

MassMEDIC strongly urges that the review performance metrics contemplated by MDUFMA be measured by the same methods for both CDRH and CBER, and that the metrics be tracked and published separately for each center.

In order to successfully meet the performance mandates of MDUFMA, we propose the following practices for CBER's implementation of MDUFMA.

- CBER should establish and publish a guideline similar to the CDRH guideline regarding recognition of international standards. This guideline should include

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standards that are applicable to blood banking and transfusion services, e.g., the American Association of Blood Banks Standards for Blood Banks and Transfusion Services.

- CBER should adhere to existing guideline "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notification," or otherwise publish a clear definition what constitutes a special, abbreviated and traditional 510(k) for submission to CBER.

- CBER should provide reasonable statistical rationale for clinical data included in a 510(k). For example, conducting *in vitro* studies to detect a 10% difference with 95% confidence between two groups of inherently variable biological systems, e.g., platelets, that has been demanded by CBER in the past, usually requires a very large sample size and is prohibitively expensive. A more generally accepted clinical approach**, and one that FDA has accepted in the past when presented with statistical rationale,** is detecting a 20% difference with 90% confidence. We believe that this approach should be consistently applied to clinical studies that measure complex and variable biological systems.

- There should be less emphasis on particulars of operator manuals. As long as the basic regulatory requirements for device labeling have been met, manufacturers are required under Design Controls, 21 CFR Part 820.30 to conduct thorough risk assessment which determines appropriate warnings, cautions, and other information to be emphasized in product manuals and literature.

In closing, MassMEDIC encourages CBER to align its activities with those of CDRH in the implementation of MDUFMA requirements and appreciate the opportunity to provide input on CBER's operations relative to MDUFMA implementation.

Sincerely,

Thomas J. Sommer
President