AMDR
Association of Medical Device Reprocessors

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BY HAND DELIVERY

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

Re: MDUFMA's Validation Data Provisions For Reprocessed "Single Use" Devices; Docket No. 02N-0534

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the Food and Drug Administration's (FDA) February 4, 2003 Federal Register notice soliciting input on the implementation of the Medical Device User Fee and Modernization Act of 2002's (MDUFMA) new requirements for reprocessed "single use" devices.[1] AMDR is a Washington, D.C.-based trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for single use. It is estimated that AMDR members perform approximately 95% of the third-party reprocessing done in the United States.

The purpose of these comments is to provide FDA with input on the implementation of Section 302(b) of MDUFMA, which requires the agency to identify those "devices or types of devices" for which reprocessed device 510(k) submissions must include "validation data" in order to ensure that the reprocessed device is substantially equivalent to a predicate device. In addition to issuing a list in the Federal Register of the "devices or types of devices" whose 510(k) submissions will require "validation data," we understand that the agency plans to promulgate guidance specifying the type of "validation data" that will be required.

As a threshold matter, AMDR notes that, to date, AMDR member companies have received clearance for numerous 510(k) submissions, many containing validation data required by FDA. Consistent with its mandate to protect public health, FDA would not have cleared these submissions had they not contained sufficient data to provide a reasonable assurance of safety and effectiveness and to demonstrate substantial equivalence to a predicate device. Thus, the type of validation data already submitted by AMDR members in their 510(k) submissions (described in Section I below) is,

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[1] Medical Device User Fee and Modernization Act (MDUFMA) of 2002; Establishment of a Public Docket, 68 Fed. Reg. 5643 (2003).

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by definition, adequate and appropriate. As such, there is no public health rationale for the agency to modify its existing validation data requirements for reprocessed device 510(k) submissions.

As discussed in Section II below, should FDA decide to depart from its existing validation data requirements, the agency must be mindful of Congress' intent that MDUFMA's validation provisions be implemented in a flexible manner that imposes the least possible burden on reprocessors.

I. The Validation Data Already Submitted by AMDR Members are Adequate and Appropriate.

Numerous reprocessed device 510(k) submissions containing "validation data" have been cleared by FDA. While some submissions may have used different terminology, and Office of Device Evaluation (ODE) reviewers may not have asked for exactly the same information in every submission, these cleared 510(k)s all contained similar types of "validation data." AMDR urges FDA to continue to allow reprocessed device 510(k)s to be cleared with the same or similar data that have been submitted in previously cleared 510(k)s. As stated above, these data are adequate and appropriate. Any guidance issued by FDA defining the type of "validation data" necessary to meet requirements of Section 302(b) of MDUFMA should be limited to the following:

- Submission of a pre-production validation program;
- Submission of a cleaning validation protocol;
- Submission of a summary of sterilization data obtained from validation using an industry standard (e.g., AAMI/ANSI/ISO 11135);
- Submission of validation data from pre-production testing; and
- Submission of a process flowchart of the reprocessing method.

II. Any New Validation Requirements Must Be Imposed In a Flexible Manner That Puts the Least Possible Burden On Reprocessors.

In the previous Section, we described the general type of validation data contained in the numerous reprocessed device 510(k) submissions that already have been cleared by FDA. The agency would not have cleared these submissions if they lacked sufficient validation data to provide a reasonable assurance of safety and effectiveness and to demonstrate substantial equivalence to a predicate device. Thus, there is no public health rationale for FDA to depart from its existing validation data requirements.

Should FDA nonetheless decide to alter its validation data requirements for reprocessors, we urge the agency to do so consistent with Congress' express intent that such requirements be imposed flexibly, in a manner that puts the least possible burden on reprocessors. In this regard, the House of Representatives report accompanying the Committee on Energy and Commerce's consideration of MDUFMA stated:

> The Committee intends that the Secretary have flexibility in determining the type of validation data required under Section 510(o)(1)(A), and that the Secretary only require the type of validation data that are necessary to protect public health. In determining the type or types of data to be submitted for FDA's review, the Secretary should be mindful of FDAMA, which obligates FDA to impose the least burdensome requirements on companies seeking premarket clearance/approval of their devices.[2]

In drafting MDUFMA, Congress understood the benefits that hospitals achieve through utilizing reprocessed devices, and wanted to ensure that MDUFMA's requirements would in no way disrupt hospitals' access to reprocessed devices:

> The Committee recognizes that there are cost savings associated with using devices that have been reprocessed. Therefore, we want to ensure access to safe and effective reprocessed devices. FDA's current regulatory scheme creates certain barriers for those in the business of reprocessing devices. We want to eliminate those barriers in a way that does not undercut FDA's ability to protect public health.[3]

In implementing MDUFMA's validation data requirements, it is vitally important that FDA refrain from erecting new regulatory barriers that will limit hospitals' access to reprocessed devices.

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2 H. R. Rep. No. 107-728, at 45-46 (2002); *See also*, Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 205 (1997) (codified as amended at 21 U.S.C. § 360c(a)(3)).

3 *Id.* at 44.

AMDR appreciates the opportunity to provide FDA with comments on this important matter. Should the agency have any questions regarding the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,

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Executive Director

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