August 1, 2011

By Electronic Submission

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

Re: Docket No. FDA-2011-D-0293 Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR)[1] respectfully submits the following comments in response to the notice published in the *Federal Register* by the Food and Drug Administration (FDA) on May 2, 2011, soliciting input on the agency's Draft Guidance for Industry and FDA Staff addressing the Processing/Reprocessing of Medical Devices in Health Care Settings: Validation Methods and Labeling [*hereinafter* Draft Guidance].[2]

AMDR commends FDA for issuing this guidance, underscoring the agency's commitment to advancing patient safety with regard to reprocessed medical devices. While our comments as FDA-regulated reprocessors of "*single-use*" devices (SUDs), would, at first blush, appear to be beyond the scope of the Draft Guidance for *reusable* devices, our members' experience with validated methods for reprocessing SUDs is applicable to FDA's current effort to address validation and labeling issues associated with reprocessing reusable devices.

AMDR shares the agency's commitment to ensuring that *all* reprocessed medical devices are safe and effective. Patients and clinicians expect medical devices to be processed/reprocessed properly, meaning no increased risks to patients. We view this Draft Guidance for manufacturers of reusable devices as reaffirming the agency's commitment to ensuring that *all* processed/reprocessed devices are safe and effective.

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[1] AMDR is a trade association representing the legal, regulatory and legislative interests of FDA-regulated, third-party reprocessors of medical devices labeled by the original manufacturer as for "single-use." It is estimated that AMDR members perform approximately 95 percent of the third-party reprocessing in the United States today. AMDR's members serve a majority of U.S. hospitals including ALL of the honor roll hospitals, *i.e.*, the top 14 institutions nationwide as listed by U.S. News & World Report for 2010-2011. AMDR's members also serve ALL of the top 10 heart and heart surgery hospitals and 9 of the top 10 orthopedic hospitals nationwide.

[2] Draft Guidance, 76 Fed. Reg. 24494 (May 2, 2011).

AMDR believes that all reprocessors/manufacturers should be held to high standards when reprocessing or providing instructions for reprocessing medical devices – regardless of how the device is labeled *(e.g.*, reusable, single-use, etc.). AMDR commends FDA for working to improve manufacturer validations for reusable device processing/reprocessing via this guidance and provides the following input and comments for consideration.

I. FDA'S EXPERIENCE REGULATING REPROCESSED SUDs APPLIES TO ITS CURRENT GUIDANCE ON REPROCESSED REUSUABLE DEVICES

The scope of FDA's Draft Guidance specifically excludes, among other things, "processes intended to be used by reprocessors of single-use devices."[3] FDA excluded reprocessors of SUDs from the scope of the Guidance Document because the agency has long had in place a stringent regulatory framework for reprocessors of SUDs.

Since 2000, FDA has considered any reprocessor of SUDs to be a "manufacturer" and, therefore, subject to the agency's full range of medical device manufacturer requirements. Indeed, pursuant to the Federal Food, Drug, and Cosmetics Act (FDCA), FDA requires SUD reprocessors to comply with all device manufacturing requirements that apply to original equipment manufacturers (OEMs),[4] as well as some additional requirements that apply only to reprocessors.

Specifically, like all OEMs, SUD reprocessors are subject to establishment registration and medical device listing;[5] medical device reporting;[6] medical device tracking;[7] reports of corrections and removals,[8] the quality system regulation ("QSR");[9] and labeling requirements.[10] Further, a reprocessed SUD is subject to premarket review by FDA, unless the agency has, by regulation, declared the device to be exempt from premarket requirements. Unless exempt, "Class I" and "Class II" devices, whether "original" or reprocessed SUDs, are required to have cleared premarket notification submissions ("510(k)s").[11]

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[3] Draft Guidance, *supra* note 2, at 3 (citing the Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessing Single-Use Medical Devices (Sept. 25, 2006) [*hereinafter* Validation Data Guidance]).

[4] Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (August 14, 2000), at 1.

[5] 21 U.S.C. § 360 and 21 C.F.R. Part 807, subpart B.

[6] 21 U.S.C. § 360i(a) and 21 C.F.R. Part 803.

[7] 21 U.S.C. § 360i(e) and 21 C.F.R. Part 821.

[8] 21 U.S.C. § 360i(f) and 21 C.F.R. Part 806.

[9] 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820.

[10] 21 U.S.C. § 352 and 21 C.F.R. Part 801.

[11] 21 U.S.C. § 360(k).

With regard to premarket review, SUD reprocessors are subject to *more stringent* regulation by FDA than are OEMs[12] because, pursuant to provisions added to the FDCA in 2002 by the Medical Device User Fee and Modernization Act ("MDUFMA"), FDA withdrew the exemptions from the premarket notification requirement for a significant number of previously exempt reprocessed devices, although the "original" devices remain exempt from premarket review.[13]

Further, reprocessors must, in most cases, include in their premarket submissions a whole category of data that OEMs are not required to submit.[14] Specifically, reprocessors are, in many cases, required to include "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended,"[15] thus, demonstrating that reprocessing produces devices that are substantially equivalent to "original" devices. By contrast, OEMs, who also must validate their processes as part of their quality system, are not required to submit such data to FDA on a premarket basis.

The reprocessing of medical devices originally labeled for "single use" is subject to a stringent, comprehensive regulatory scheme. In short, "FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device."[16]

The result of FDA's stringent regulatory requirements for SUD reprocessors is that reprocessed SUDs are as safe and effective as original devices and pose no increased risk to patients. In addition to the decade of safe clinical use, both FDA and the independent U.S. Government Accountability Office (GAO) have concluded that there is no evidence of harm to patients from FDA-regulated reprocessed devices.[17]

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[12] *See* Testimony of Dr. Daniel Schultz, Director, CDRH, FDA (September 26, 2006) ("Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the agency that exceeded the requirements for the original manufacturers (OEMs)") (emphasis added) [*hereinafter,* Schultz testimony].

[13] Title III of MDUFMA amended the FDCA (Public Law 107-250). The law required FDA to identify "critical" and "semi-critical" 510(k)-exempt devices for which the exemptions should be terminated when the devices are reprocessed, "in order to provide a reasonable assurance of the safety and effectiveness of the devices" (21 U.S.C. § 360(o)). For devices that lost exemption from the premarket notification, reprocessors had to submit a 510(k) within 15 months of FDA's publication of a notice terminating the exemption, or the device in question could no longer be legally marketed. 21 U.S.C. § 360(o)(2)(B)*; see also* 68 Fed. Reg. 38071 (June 26, 2003).

[14] MDUFMA requires that the labeling of reprocessed devices bear the reprocessor's name and state that the device was reprocessed. 21 U.S.C. § 352(v), effective January 25, 2004. The law also requires that, in most instances, reprocessors include validation data in their premarket submissions. 21 U.S.C. § 360(o)(2)(B)*; see also* 68 Fed. Reg. 38071, *supra* note 13.

[15] 68 *Fed. Reg.* 23139 (April 30, 2003), *citing* 21 U.S.C. § 360(o) (emphasis added). For a description of some of the validation data reprocessors must submit on a premarket basis, including more particular guidance on cleaning, functional testing, and sterilization data requirements, *see* Validation Data Guidance, *supra* note 3, at 15.

[16] Schultz testimony, *supra* note 12.

[17] U.S. Government Accountability Office, GAO-08-147, *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk* (January 2008), at 14-19 (emphasis added). which, among other things, concluded, "After reviewing the available evidence—including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's

AMDR is proud to have worked with FDA to ensure that our reprocessed SUDs are safe and effective for clinicians and patients. The leadership demonstrated by FDA in choosing to legitimize the third-party SUD reprocessing industry through regulation is now looked at as a model. AMDR believes that FDA is again poised to demonstrate the leadership it exhibited in regulating SUD reprocessing with these new activities, including this Draft Guidance, aimed at encouraging proper reprocessing of reusable devices.

II. AMDR-MEMBERS CURRENTLY COMPLY WITH THE VALIDATION PROCESSES PROPOSED IN THE DRAFT GUIDANCE AND PROVIDE VALIDATION DATA TO FDA ON A PREMARKET BASIS

As stated above, and consistent with the validation methods proposed in FDA's Draft Guidance for the reprocessing of reusable devices, third-party SUD reprocessors already perform reprocessing validations and generally this validation data is subject to premarket review. Pursuant to FDA's guidance, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices, as authorized by the Medical Device User Fee and Modernization Act of 2002, SUD reprocessors are required to submit to FDA, on a premarket basis, validation data on cleaning, sterilization and functional performance demonstrating that the reprocessed SUD remains substantially equivalent to the predicate device after the maximum number of times the device has been reprocessed.[18]

In applying these increased data requirements for SUD reprocessors, FDA relied in large part on AAMI's Technical Information Report (TIR) 30[19]. For example, third-party reprocessors conduct worst-case cleaning validations, employ artificial or native test soils to inoculate devices as part of cleaning validations, and test for meaningful levels of clinically relevant soil – all of which FDA now recommends be undertaken by OEMs to validate the proper reprocessing of their reusable devices. FDA began requiring SUD reprocessor compliance with the principles outlined in TIR 30 on a *premarket basis* as far back as 2004 – requirements that currently do not exist on a *premarket basis* for OEMs. As such, validation data is provided as part of most SUD reprocessor premarket notifications.

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consultations with hospital representatives—we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat" (emphasis added).

[18] Validation Data Guidance, *supra* note 3.

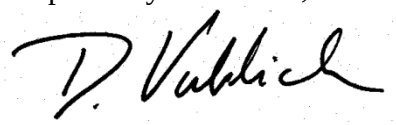
[19] In fact, AMDR holds a voting seat on AAMI's technical committee, "Cleaning of Reusable Medical Devices Working Group 93 (for TIR 30),"[19] underscoring the importance of the TIR to the nation's third-party SUD reprocessing industry. *See* Association for the Advancement of Medical Instrumentation (AAMI), Technical Information Report: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices (AAMI TIR 30; 2011). Note, a revised TIR is expected to be issued in 2011, thus the new date.

AMDR commends FDA for strengthening the premarket validation requirements for OEMs of reusable devices through this Draft Guidance. However, AMDR encourages the agency to not only require that OEMs include validated labeling instructions in their premarket notifications *but also* require OEMs to provide the underlying cleaning, sterilization and functional performance validation data. As mentioned above, reprocessors of SUDs have been required to provide such validation data on a premarket basis since 2004. Such an approach would harmonize the treatment of reprocessed devices (regardless of whether they are single-use or reusable) and, more importantly, help ensure that potential safety issues stemming from inadequate validations are reviewed by the agency before problems arise in the clinical setting.

On behalf of AMDR, we appreciate the agency's time and attention to these matters.

Thank you.

Respectfully Submitted,



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