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Re: Docket # 03N-0016

AdvaMed
Advanced Medical Technology Association

August 8, 2003

Lily Ng
Office of Surveillance and Biometrics, CDRH
Food and Drug Administration
1350 Piccard Drive
Room 360-H
Rockville, MD 20850

Re: AdvaMed's Answers to FDA's MedWatch Questions

Dear Lily:

We appreciate the opportunity to respond to FDA's specific questions regarding the implementation of Section 303 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). Your questions were the catalyst for several meetings with our members so that we could provide complete responses to your questions. As often happens, we found that what appeared to be simple and straightforward questions turned out to be more complicated and difficult than we originally anticipated.

How many members are affected by the changes to the MedWatch form?
The proposed change to the MedWatch forms mandated by Section 303 of Medical Device User Fee and Modernization Act of 2002 (MDUFMA) directly affects user facilities, distribution centers, and importers by requiring these entities to report whether single-use devices (SUDs) are reprocessed and, if so, the name and address of the reprocessor. The statute does not contemplate device manufacturers responding to the questions. Nonetheless, all device manufacturers will be impacted by any change to the form. Any revision to the MedWatch form will require manufacturers to incorporate the new change(s) into their reporting systems, which may include validation of affected computer systems used for electronic submissions and electronic record keeping.

What information do OEM's have regarding whether a device is reprocessed? Do manufacturers know if a device is reprocessed or who the reprocessor is?
There are no affirmative mechanisms that allow original equipment manufacturers (OEMs) to detect when SUDs have been reprocessed or to know who the reprocessor may be. To the contrary, user facilities are frequently reluctant to acknowledge to OEMs that they reprocess

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single-use devices. For these reasons, AdvaMed proposed narrowly drawn language as part of MDUFMA that would have required reprocessors, where feasible, to brand reprocessed single-use devices. This would have provided a mechanism to identify most reprocessed SUDs and the involved reprocessors. Unfortunately, the language of Section 301 was broadened to include all devices – an expansion that will be difficult to implement.

Conflict Between Section 303 of MDUFMA and Existing Regulations

We would like to bring to your attention our concerns about the apparent conflict between the requirements of Section 303 of MDUFMA and the existing requirements of 21 CFR 803.52(f)(11)(i) and (iii). Section 303 requires FDA to revise the MedWatch forms to require questions about whether an SUD was reprocessed, and if so, to provide the name and address of the reprocessor. This information is required to be provided by user facilities and importers. However, 21 CFR 803.52(f)(11)(i) and (iii) require manufacturers to provide corrected data, including: (i) "any information missing on the user facility report or distributor report, including missing event codes, or information corrected on such forms after manufacturer verification" and (iii) "if any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information." We understand and strongly support the intent behind 21 CFR 803.52(f)(11): to ensure full and accurate reporting even when user facilities fail to report. However, as explained above, there are no affirmative mechanisms for OEMs to determine whether devices have been reprocessed. While the language of Section 303 is clearly targeted to user facilities and importers, not manufacturers, manufacturers are required by 21 CFR 803.52(f)(11) to ultimately provide this information or an explanation of why such information was not provided and the steps taken to obtain such information from the user facilities or importers.

Recommendations for Changes to MedWatch Form 3500 and 3500A

We have several recommendations which we believe will better fulfill the Congressional intent of Section 303 of MDUFMA and will help resolve the above-referenced conflict.

To better comply with the Congressional intent behind Section 303, we recommend that the new questions regarding whether an SUD was reprocessed and the name and address of any such reprocessor be added to section F (to be completed by the user facility/importer) of mandatory reporting form 3500A. User facilities should be asked "Is this a Single-Use Device that was reprocessed and reused on a patient" and should be provided only two boxes labeled "yes" or "no." If the answer is yes, user facilities should provide the name and address of the reprocessor. Any omitted answer to these questions in section F would indicate the user facility's or importer's failure to provide the mandated information on the reprocessed status of the device.

To resolve the apparent conflict between Section 303 and the existing regulations, we recommend that the questions regarding whether an SUD was reprocessed and the name and address of any such reprocessor *also be added* to section H (to be completed by the

manufacturer) of mandatory reporting form 3500A. However, for section H only, we recommend that FDA include three boxes labeled "yes," "no," or "unknown." The addition of the box labeled "unknown" addresses the issue of an OEM's inability to affirmatively know whether a device has been reprocessed and who the reprocessor was. In those few circumstances where the manufacturer can determine the reuse status of an SUD, they would indicate that in the "yes" or "no" boxes.

We do not believe that question #8 of section H can be used for this purpose. It is our understanding that question #8 applies to reusable devices. We recommend that this be made clear in the revisions to the mandatory form.

AdvaMed also recommends that the voluntary Form 3500 be revised to include the reprocessed SUD questions in section D, "Suspect Medical Device." This allows the user facility or importer to accurately provide the information mandated by Section 303 of MDUFMA for the voluntary form.

Can we agree to a shorter timeframe?
With respect to a shorter implementation timeframe, as we indicated in our initial comments to the docket, we believe that for many manufacturers it will take at least two years to modify and validate their reporting systems to comply with the new requirements. Validation of the revised form must be considered in the context of numerous validation projects all competing for the same IT resources. The validation must be planned, budgeted, and scheduled. Further, some companies may have numerous systems that will require modification and validation and which must be planned for and budgeted. Nevertheless, AdvaMed understands FDA's views on the urgency of implementing this new requirement as soon as possible and revisited the matter with our member companies.

Recommendations for Interim One-Year Period
As an alternative, we recommend that FDA require user facilities to immediately begin providing the reprocessing responses and to allow a one-year interim period (from the date that the new MedWatch form is issued) during which user facilities, importers and manufacturers could use the old forms to submit the new required information on the voluntary and mandatory reporting forms.

We recommend that user facilities be required to provide the information in section B "Adverse Event or Product Problem," # 5 "Describe event or problem" whether they are reporting on the voluntary Form 3500 or the mandatory Form 3500A.

In those instances where device manufacturers can discern the reprocessing status of the device, that information could be provided in section H. "Device Manufacturers Only," #10 "Additional manufacturer narrative." We believe the one-year interim period will provide companies enough time to modify and validate their systems.

FDA Controls Important Aspects of the Implementation Timeframe
Finally, a determining factor in promptly implementing the new requirements of Section 303 lies with FDA. Manufacturers who use the EDI Phase I program have brought to our attention the fact that their ability to quickly implement changes to the MedWatch form will depend in large part on FDA's timeframe for making changes to the EDI Phase I program to integrate the new MedWatch form. For example, EDI Phase I users will need to test their systems with FDA to validate that they work post change. In addition, FDA must be in a position to accept the new modified format from industry before industry makes changes. We would like to better understand FDA's timeframe for implementing any needed changes to EDI Phase I.

Conclusion
In conclusion, we share your goals and objectives with respect to implementing Section 303 as quickly as possible. AdvaMed appreciates the opportunity to work with FDA on this important issue. To that end, we respectfully request a meeting with you to further discuss our recommendations and to work with you to satisfactorily resolve the issues.

Sincerely,

Brian Mayhew
Director
Technology and Regulatory Affairs