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March 17, 2004

David W. Feigal, M.D., M.P.H.  
Director  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd., HFZ-01  
Rockville, MD 20850

**Re: *Failure of Third-Party Reprocessors of Single Use Devices to comply with timelines set forth in Sec. 302 of the Medical Device User Fee and Modernization Act (MDUFMA).***

***Submitted to:***

***Docket No. 03N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.***

***Docket No. 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA)***

Dear Dr. Feigal:

On behalf of AdvaMed<sup>1</sup>, we are writing to ask the Food and Drug Administration to initiate timely and appropriate action to deal with the illegal products of those third-party reprocessors of Single Use Devices (SUDs) who have failed to comply with timelines set forth in Section 302 of MDUFMA. Specifically, the April 30, 2003 *Federal Register* (FR) Notice No. FR03-10413 specified:

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<sup>1</sup> AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems, ranging from the largest to the smallest innovators and companies. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the \$75 billion in health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world.

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*“Manufacturers who already have clearance letters for SUDs identified in List II must submit validation data for these devices by **January 30, 2004, or marketing of these devices must cease.**” (emphasis added)*

List II refers to the list of reprocessed SUDs that were subject to the new MDUFMA 510(k) requirements and determined by FDA to be either high-risk or intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). Pursuant to the FR Notice, those reprocessors who had existing clearances for devices that appeared on List II had until January 30, 2004 to submit validation data regarding cleaning, sterilization, and functional performance to support the reprocessing of the SUD. In a February 17, 2004 meeting with CDRH officials, AdvaMed representatives were told that reprocessors had failed to submit 510(k) applications for the vast majority of the reprocessed SUDs subject to the January 30, 2004 deadline. This is a disturbing development which warrants an appropriate and timely response from the Agency for the reasons enumerated below.

#### **Patients are at Increased Risk**

The failure of reprocessors to provide validation data to support the cleaning, sterilization and functional performance of the reprocessed SUDs strongly suggests that the reprocessors either (1) do not have the data or (2) have data which the reprocessors themselves have determined are inadequate to support the reprocessing of the listed SUDs. In either case, these devices would not only violate the implementing requirements of Section 302 of MDUFMA, but would also violate the principals and specific requirements of Subpart G of the Quality System Regulation (QSR) (21 CFR 820) published October 7, 1996. MDUFMA merely created the requirement for *premarket review* of validation data – not the requirement for the *existence* of the data.<sup>2</sup> The ability to validate non-verifiable processes (such as sterilization or the removal of infectious agents) is fundamental in a Quality System to assure the safety and effectiveness of medical devices. If reprocessors cannot produce adequate data to support the cleaning, sterilization and functional performance of the reprocessing of the identified high-risk SUDs, it must be concluded that continued distribution of these devices represents an unreasonable risk of harm to patients.

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<sup>2</sup> Indeed, more than 4 years ago, Mr. Vern Feltner, President of Alliance Medical Corporation, representing the Association of Medical Device Reprocessors (AMDR) emphasized in both verbal and written testimony before the House Commerce Subcommittee on Oversight and Investigations that “Reprocessors must comply with FDA QSRs just like manufacturers[.]” and “The fact is that third-party reprocessors are currently required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation.” Hearing on Reuse of Single-Use Medical Devices, Subcommittee on Oversight and Investigations of the Committee on Commerce, February 10, 2000, Serial No. 106-89; pgs. 124 & 126.

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**Reprocessors are in Violation of the Law**

The failure of reprocessors to provide validation data by the designated timeline (which implements the provisions of Section 302 of MDUFMA) is a failure to comply with the law. The reuse provisions of MDUFMA were enacted by Congress to assure adequate controls are in place to provide a reasonable assurance of the safety and effectiveness of reprocessed SUDs. Further, the failure to provide validation data for such a substantial portion of the listed reprocessed SUDs suggests not only the absence of product-specific data – but the absence of an adequate and appropriate *system* for assuring the collection and maintenance of these data.

The requirement for having a system in place to generate and maintain these data derives directly from the Quality System Regulation (21 CFR 820) published in 1996. The fact that commercial reprocessors are subject to the QSR has been communicated to industry (OEMs and reprocessors) numerous times over the past years. For example, in response to a September 5, 1997 citizen petition filed by HIMA which requested that FDA require commercial reprocessors of disposable medical devices to comply with all applicable FDA regulations governing medical device manufacturing, Dr. Bruce Burlington wrote<sup>3</sup>:

*“These reprocessors are inspected in accordance with the current Quality System regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and they are subject to the labeling requirements of 21 CFR Part 801. This has been FDA’s position for some time, as evidenced in a December 27, 1995 letter to trade associations from Lillian Gill, Director, Office of Compliance, CDRH. . . . In fact, FDA has considered such reprocessing firms to be manufacturers under the GMP regulations promulgated in 1978 and continues to consider them as such under the Quality System regulation . . . .”*

Furthermore, FDA communicated explicit expectations with respect to validation of reprocessing to commercial reprocessors in a draft Guidance published on June 1, 2001<sup>4</sup> which, in part, stated:

*“. . . Validations should meet general norms, addressing the issues of both product performance and risk of infection. . . . Tests used to support the design specifications and quality control procedures should include SUD samples exhibiting the range of tolerances for the specifications and*

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<sup>3</sup> Letter to Nancy Singer, Esq., then Special Counsel to the Health Industry Manufacturers Association, July 13, 1998. Reference Docket No. 97P-0377.

<sup>4</sup> Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff, June 1, 2001.

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*procedures. For example, cleaning, sterilization, and performance tests should include SUDs with the range of potential contamination and wear which the reprocessor intends to accept and process from incoming product. . . . Cleaning protocols and simulations should be rigorous and relevant. The soil should relate to the environment of use. Soil reduction, per se, should be insufficient as an endpoint. Elimination of visible soil is a qualitative endpoint that should be coupled with a quantitative assessment."*

Despite the fact that commercial reprocessors have always been subject to the requirements of the QSR, the majority of devices<sup>5</sup> are reprocessed by companies which have received Warning Letters which have cited, in part, failure to conform to validation requirements of the QSR. For example, in a December 1997 Warning Letter to Sterile Reprocessing Services (part of Alliance Medical Corporation)<sup>6</sup> following an inspection, FDA cited numerous QSR violations, including:

*"Failure to, where the results of a process cannot be fully verified by subsequent inspection and test, validate the process with a high degree of assurance . . . ."*

Furthermore, in 1999 and 2001, Alliance Medical Corporation received additional Warning Letters<sup>7,8</sup> citing numerous violations of the QSR, including:

*"Failure to establish and maintain procedures for validating the device design to ensure that devices conform to defined user needs and intended uses, as required by 21CFR 820.30(g)."*

*". . . failed to adequately perform design validation, in that you have not determined the negative consequences of multiple reprocessing and have*

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<sup>5</sup> As of March 12, 2004, the website for the Association of Medical Device Reprocessors (AMDR) states "...Approximately 95% of the third-party reprocessing done in the United States is performed by three companies, which collectively comprise the membership of [AMDR]." Two of these three companies are Vanguard Medical Concepts and Alliance Medical Corporation.

<sup>6</sup> Warning Letter to Mr. Horace P. Goodrich, President, Sterile Reprocessing Services; 98-DAL-WL-10; December 18, 1997

<sup>7</sup> Warning Letter to Mr. Rick Ferreira, CEO, Alliance Medical Corporation; FLA-00-17; December 23, 1999

<sup>8</sup> Warning Letter to Mr. Mark Ferreira, President, Alliance Medical Corporation; 01-ATL-61; July 13, 2001

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*not established a maximum number of reprocessing operations for cardiovascular catheters.”*

and

*“ . . . failed to implement appropriate complaint handling procedures. Complaints [are] not being investigated to identify existing or potential causes of nonconforming product or other quality problems.”*

In addition, in 1999 Vanguard Medical Concepts received a Warning Letter citing multiple violations of the QSR<sup>9</sup> including:

*“Failure to validate the cleaning process with a high degree of assurance as required by 21 CFR 820.75(a).”;*

*“Failure to adequately validate the sterilization process as required by 21 CFR 820.75. For example: (a) No information was available or submitted to demonstrate that the sterilization process has no adverse impact on the devices that are processed. . . . (b) Information regarding the effectiveness of the process does not demonstrate that the process will consistently and effectively achieve the specified sterility assurance level of 10<sup>-6</sup>.”;*

and

*“Failure to ensure that validated processes are performed by qualified individuals as required by 21 CFR 820.75 (b)(1). For example, the person most responsible for process validation has not received training in this area.”*

In sum, two of the three companies responsible for the reprocessing of the majority of single use medical devices distributed in the United States have an inspectional history which suggests either an inability or an unwillingness to comply with the specified requirements of the QSR – a violation of the law. Commercial reprocessors have now further expressed their inability or unwillingness to comply with the law by failing to comply with the MDUFMA specified timelines.

### **Conclusion**

AdvaMed is very concerned about the substantial risk of patient harm that may result from the failure of reprocessors to comply with the MDUFMA timelines. Further, the failure of

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<sup>9</sup> Warning Letter to Mr. Charles A. Masek, Jr., President & CEO, Vanguard Medical Concepts, Inc.; FLA-00-01; October 14, 1999

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reprocessors to provide the validation data contributes to the impression that, in all likelihood, the data do not exist.

Congress intended that there be a reasonable assurance that reprocessed SUDs are safe and effective for the maximum number of times the reprocessor intends the device to be reprocessed. If, in fact, the data to validate the cleaning, sterilization and functional performance of reprocessed devices do not exist, then patients are at an unreasonable risk of exposure to contaminated, non-sterile and non-functioning reprocessed SUDs.

If the latter is true, it can only be concluded that those reprocessors that have failed to provide the required validation data do not have an adequate and efficacious Quality System (as required by law) which require these data to have already been in place.

Respectfully,



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