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April 23, 2003

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

***RE: Docket Number 02N-0534 Section 302 of Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Supplementary Comments***

Dear Sir/Madam:

AdvaMed, the Advanced Medical Technology Association, is pleased to provide additional comments on Section 302 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). AdvaMed represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$71 billion health care technology products consumed annually in the United States, and nearly 50 percent of \$169 billion purchased around the world annually.

As FDA approaches a key deadline in implementing Section 301, AdvaMed submits this letter in further support of its February 2003 recommendations concerning the validation data and 510(k) exemption termination provisions for certain reprocessed single-use devices. We also take this opportunity to address some comments subsequently submitted to FDA that do not recognize what the law requires of the agency to effectively implement these provisions.

By April 26, 2003, MDUFMA requires FDA to identify those reprocessed single-use devices for which the agency will require the submission of validation data. By that same date, FDA also must determine which 510(k) exemptions for critical reprocessed single-use devices are to be terminated. We believe that FDA must aggressively and thoroughly implement these provisions and meet its responsibilities under the law. To do otherwise would limit or nullify the public health purpose in enacting these provisions to address specific and real concerns with reprocessed single-use devices.

02N-0534

C 27

**Validation Data**

After AdvaMed submitted its February 2003 comments on validation data, the agency received a comment that asserted that previously cleared 510(k) submissions already contained validation data that were “by definition, adequate and appropriate,” thus implying that the agency need not revisit already cleared 510(k)s. *See* Association of Medical Device Reprocessors’ Comment Re MDUFMA’s Validation Data Provisions (March 19, 2003). The comment further argued, “FDA should 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.” These assertions fail to appreciate the law itself or the Congress’s intent in enacting it.

Under section 302(b), Congress mandated that for “reprocessed single-use devices for which reports are required under subsection (k)”, FDA must identify those “devices or types of devices” for which a premarket notification “must ... include validation data, the types of which shall be specified by [FDA], regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.” § 302(b) of MDUFMA (§ 510(o)(1)(A) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). Congress expected the agency to determine which types of reprocessed single-use devices or device types, including those previously cleared, would now be required to submit the newly identified validation data. This provision specifically applies “to reprocessed single-use devices for which reports are required under subsection (k)” (emphasis added); it was written to cover all single-use reprocessed devices subject to premarket notification, past, current and future. Had it been intended only to cover future 510(k) single-use reprocessed devices, the provision would have stated “devices or types of devices for which reports will be required.” In other words, subsection 510(o)(1)(A) clearly covers reprocessed single-use devices that received 510(k) clearance prior to the enactment of MDUFMA and prior to April 26. FDA must review each reprocessed single-use device or type of device that was subject to 510(k) at all times prior to April 26, 2003.

This indisputable conclusion is fully buttressed by paragraph (1)(B) which requires persons, who submitted 510(k)s prior to the publication of the agency’s list, to submit the required validation data no later than nine months after the list’s publication. *See* § 302(b) of MDUFMA (§ 510(o)(1)(B) of the FD&C Act). This includes persons who received substantial equivalence determinations for their reprocessed single-use devices prior to the enactment of MDUFMA. *See* H.R. Rep. No. 107-728, Part 2, at 10 (2002) (stating, “In the case of reprocessed single-use devices that, under current law, are required to submit a premarket notification submission under section 510(k) of the act, the Secretary would review those submissions (including those already approved prior to enactment of the bill)”).

and publish a list of reprocessed single-use devices for which validation data, as described above, is required to ensure that the reprocessed device is substantially equivalent to a predicate device.”) (emphasis added). Congress provided a nine month period to submit the required validation data to ensure fairness to persons who already received 510(k) clearance from FDA for their reprocessed single-use devices. Despite the grace period, the statute and its legislative history make it clear that a failure to submit validation data, demonstrating that a reprocessed single-use device “will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification”, § 510(o)(1)(A), will result in the 510(k) clearance being withdrawn, *see* §510(1)(B); H.R. Rep. No. 107-728, at 46 (2002) (explaining that the Committee included a grace period in the legislation, but that if a party fails to submit the validation data on time, then FDA should issue a not substantially equivalent order for the device “thus resulting in its removal from commercial distribution”).

Simply stated, MDUFMA fully contemplates the agency re-examining all reprocessed single-use devices with cleared 510(k)s, whether or not their original 510(k)s included some form of validation data. Indeed, contrary to the commenter’s argument that “the type of validation data already submitted by AMDR members in their 510(k) submissions . . . is, by definition, adequate and appropriate”, March 19, 2003 Comment Re Validation Data Provisions at 1-2, we believe the better argument is that Congress knew exactly what it was doing, and believed that FDA’s past clearances of reprocessed single-use devices relied upon inadequate validation data to substantiate sterilization and cleaning instructions and functional performance of such devices after the maximum number of intended reprocessings. AMDR’s statement that “there is no public health rationale . . . to modify [FDA’s] existing validation data requirements for reprocessed [single-use] devices”, simply relegates Congress’s validation provision to fluff, assuming that Congress passes laws requiring specific actions from FDA and industry for no reason. This type of thinking is unacceptable because it simply ignores Congress’s stated intent to “identify reprocessed single-use devices for which it determines that validation data . . . are needed to ensure that the device will remain substantially equivalent to its predicate after the maximum number of times the device is reprocessed as intended by the reprocessor.” H.R. Rep. No. 728, 107th Cong., 2d Sess. 45. Thus, Congress’s charge to the FDA is supported by a substantial public health rationale that the agency must ensure that reprocessed single-use devices remain substantially equivalent to their predicates. Simply put, FDA must now make determinations about the maximum number of intended reprocessings of a given device based on validation; something FDA has not done in the past.

### **Termination of 510(k) Exemptions**

Likewise, it is critically important that FDA appreciate the responsibility Congress placed on the agency in re-evaluating 510(k) exemptions for reprocessed single-use devices. For

“critical or semi-critical reprocessed single-use devices” that are class I or class II exempt devices, FDA must “identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices.” § 302(b) of MDUFMA (§ 510(o)(2)(A) of the FD&C Act). For critical devices, the agency’s deadline for publishing this list is April 26, 2003. *See* § 302(b) (§ 510(o)(2)(C) of the FD&C Act, which also establishes an April 26, 2004 deadline for the agency to publish the list of semi-critical devices).

Congress focused on re-evaluating the 510(k) exemptions for critical and semi-critical reprocessed single-use devices because by their very nature these devices present the greatest health risks. Specifically, a critical reprocessed single-use device “is intended to contact normally sterile tissue or body spaces during use.” § 302(d) of MDUFMA (§ 201(mm)(1) of the FD&C Act). A semi-critical reprocessed single-use device “is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.” § 302(d) of MDUFMA (§ 201(mm)(2) of the FD&C Act). Because of these intended uses and because reprocessing a single-use device could create unexpected results, these reprocessed devices require a close scrutiny over and above that required for an original single-use device. As Congress stated, “*reprocessing may, in certain circumstances, raise issues* (e.g., related to appropriate cleaning and/or sterilization, and functional performance) to warrant review by FDA.” H.R. Rep. No. 28, 107<sup>th</sup> Cong., 2d Sess. 46 (emphasis added).

Unexpected results from reprocessing may occur, and may be expected, because single-use devices are designed for only one use. Indeed, we respectfully but vigorously disagree with one comment’s assertion that “OEMs cannot be regarded as experts on the ‘reprocessability’ of devices that they choose to label as ‘single-use.’” *See* Association of Medical Device Reprocessors Comment Re 510(k) Exemption Provisions (March 19, 2003). It is precisely because of our members’ expertise, experience, and design knowledge of single-use devices that causes us to be concerned with the reprocessing of single-use devices. Our members fully understand the design limitations of their single-use devices and label them accordingly. Subsequent use can be hazardous, particularly when a device is repeatedly reprocessed and sold as a single-use product despite the fact that no validation supports the cleaning, sterilization or performance of the device after multiple reprocessings. Indeed, our February recommendations for the termination of exemptions for certain devices were based, in part, on specific design concerns that AdvaMed members identified precisely because of their expertise in designing these devices. *See* AdvaMed Comment to Docket Number 02N-0534 (Feb. 7, 2003) (for example, recommending the termination of the exemption for ENT Burrs/Blades because “curved blades cannot be disassembled for cleaning – the spring section cannot be accessed or cleaned”).

When Congress initially exempted class I devices and permitted FDA to exempt certain class II devices, there is absolutely nothing to suggest that Congress was thinking about exempting

reprocessed single-use devices from premarket notification. Indeed, the agency's regulations at the time imposed a limitation on 510(k) exemptions that arguably disqualified reprocessed single-use devices from an exempt status. *See e.g.*, 21 CFR § 876.3 (1994). Nonetheless, FDA has regulated a number of reprocessed single-use devices as 510(k) exempt and Congress had enough concern for the public health that a review of the exempt status of such devices is now required.

AMDR argues that FDA always had the authority to remove 510(k) exemptions from devices, and therefore, its failure to do so supports a conclusion that there is no public health need now for the agency to terminate any exemptions. *See* March 19, 2003 Comment Re Exemption Provisions at 1-3. AMDR also relies on an FDA June, 2001 denial of a petition to remove an exemption for non-electric biopsy forceps. *See id.* at 3-4. Neither of these arguments is persuasive.

The fact FDA failed to terminate 510(k) exemptions to date for reprocessed single-use devices only bespeaks the need for the MDUFMA's exemption termination provision. Congress provided FDA this specific reprocessed single-use device 510(k) termination authority:

in recognition of the fact that although a single-use device as originally manufactured may be of sufficiently low risk to warrant an exemption from the requirement to submit a 510(k), reprocessing may, in certain circumstances raise issues (e.g., related to appropriate cleaning and/or sterilization, and functional performance) to warrant review by FDA.

H.R. Rep. No. 728, 107<sup>th</sup> Cong., 2d Sess. 46. In other words, FDA's inaction did not impress Congress. As a result, we believe that FDA's inaction in the past is a reason itself for the agency to closely review each and every critical, and ultimately semi-critical, exempt reprocessed single-use device to determine whether a premarket notification is necessary to provide a reasonable assurance of safety and effectiveness. Of course, an FDA denial of a petition in 2001 pertaining to non-electric biopsy forceps has no weight to alter FDA's legal responsibility to review the forceps *de novo* and determine whether or not the validation required of devices that lose their exemption is necessary to provide a reasonable assurance of safety and effectiveness. Importantly, in the past FDA did not evaluate the safety and effectiveness of devices like reprocessed single-use non-electric biopsy forceps through review of validation data premised on the maximum number of times such devices would be reprocessed. Now, we contend, such an assessment is necessary to evaluate the public health impact of reprocessed single-use devices. If such an assessment is required by law for devices subject to 510(k), *see* § 510(o)(1)(A), it must also be applied to exempt devices to evaluate whether such validation data are needed to ensure safety and effectiveness, *see* § 510(o)(2)(A).

**Docket No. 02N-0534 (MDUFMA)**  
**Supplementary Comments**  
**April 23, 2003**  
**Page 6**

In sum, we believe that if the agency has no solid, scientific evidence to show that a 510(k) is unnecessary "to provide a reasonable assurance of safety and effectiveness" for any critical or semi-critical reprocessed single-use device, the 510(k) exemption for that device should be terminated on April 26, 2003 (critical devices) or April 26, 2004 (semi-critical). Accepting the views espoused by AMDR would be an acceptance of an invitation to ignore the law, an unacceptable result. Accordingly, we respectfully request that FDA accept our February 2003 recommendations requesting that certain reprocessed single-use devices have their exemptions terminated and that validation data be required for those devices specified in our February comments.

AdvaMed appreciates the opportunity to provide these comments and would like to work with the agency to ensure the appropriate implementation of these key provisions of MDUFMA.

Sincerely,



Janet Trunzo  
Vice President  
Technology and Regulatory Affairs