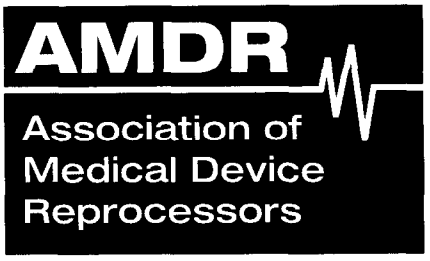

March 19, 2003

BY HAND DELIVERY

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

Re: MDUFMA's 510(k) Exemption 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 any "critical" or "semi-critical" reprocessed single use devices that are currently exempt from 510(k) submission requirements, but whose exemptions should be terminated "in order to provide a reasonable assurance of the safety and effectiveness of the devices." If FDA determines that certain exemptions should be terminated, the agency is required to publish a list in the Federal Register of the applicable "critical" devices by April 26, 2003, and a list of the applicable "semi-critical" devices by April 26, 2004.[2]

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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).

[2] MDUFMA § 302(b).

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As a threshold matter, AMDR notes that MDUFMA does not require FDA to terminate any exemptions. Rather, MDUFMA directs FDA to remove an exemption if it determines that a 510(k) is necessary to provide a reasonable assurance of safety and effectiveness. However, prior to the passage of MDUFMA, the Federal Food, Drug, and Cosmetic Act (FDC Act) already authorized the agency to impose the 510(k) requirement on any Class I device -- reprocessed or new -- if the device "[were] intended for a use which is of substantial importance in preventing impairment of human health" or "present[ed] a potential unreasonable risk of illness or injury."[3] Moreover, in its August 14, 2000 guidance document, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," FDA stated:

> At a later date, the agency will evaluate, on a case-by-case basis, the need to revoke exemptions from premarket submission requirements for class I and class II exempt products. Revocation of exemptions will be based on the agency's determination that premarket submissions for reprocessed devices in those classifications are necessary to ensure that these devices are safe and effective for reuse after reprocessing. The issuance of this guidance document does not preclude FDA from taking immediate action against any particular product that is causing significant harm.[4]

Thus, FDA did not need MDUFMA in order to terminate the exemption for a currently 510(k)-exempt reprocessed device. It always has possessed this authority, and consistent with its mandate to protect public health, the agency would have required a 510(k) submission for any currently exempt reprocessed device if there had been a safety or effectiveness reason to do so. To date, however, the agency has not revoked the 510(k) exemption for any reprocessed single use device because there has been no public health rationale for the agency to take such action.

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[3] 21 U.S.C. § 360(l).

[4] CDRH, FDA, *Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Aug. 14, 2000) at 10 [hereinafter FDA Guidance].

As discussed below, in AMDR's view, there continues to be no public health rationale for FDA to revoke the 510(k) exemption for any currently exempt reprocessed device -- and MDUFMA requires that a public health rationale exist in order for FDA to terminate an exemption.[5] In comments to the agency, the original equipment manufacturer (OEM) community has aggressively lobbied FDA to revoke the 510(k) exemption for a number of reprocessed "single use" devices, with particular emphasis on non-electric biopsy forceps. However, as detailed below, FDA already has determined that a 510(k) is not necessary to provide a reasonable assurance of safety and effectiveness for non-electric biopsy forceps, and AMDR is unaware of any credible new information that would justify the agency's reversal of this decision.

1. **FDA Already Has Determined that a 510(k) Is Not Necessary to Provide a Reasonable Assurance of Safety and Effectiveness for Non-Electric Biopsy Forceps, and There Exists No Justification for Reversing this Decision.**

In recent comments to FDA's MDUFMA docket, Boston Scientific Corporation (BSC), the Advanced Medical Technology Association (AdvaMed), and the Medical Device Manufacturers Association (MDMA) each requested that FDA terminate the 510(k) exemption for non-electric biopsy forceps (21 C.F.R. § 876.1075(b)(2)). Significantly, BSC made this same request in a Citizen Petition submitted on September 20, 2000.[6] Specifically, BSC asserted that:

> It is clear that single-use non-electric biopsy forceps reprocessed without 510(k) clearance are not safe or effective for reuse. It is BSC's position that FDA must immediately revise the regulation which exempts all non-electric biopsy forceps from premarket notification procedures to exclude single-use non-electric biopsy forceps that have been reprocessed.[7]

On June 28, 2001, FDA denied BSC's petition, stating:

> FDA concludes that when produced in compliance with general controls, particularly Quality System requirements, reprocessed biopsy forceps will attain proper sterility and performance and thus do not present a potential unreasonable risk of illness or injury. . . . With such general controls in place, FDA finds that

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5 *See* MDUFMA § 302 (b) ("The Secretary shall identify such devices or types of devices for which exemptions should be terminated in order to provide a reasonable assurance of safety and effectiveness of the devices").

6 Citizen Petition from Greg Barrett, Boston Scientific Corporation, to FDA (Sept. 20, 2000).

7 *Id.* at 9.

> submission of a premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness and will not further the agency's public health mission.[8]

Thus, FDA assessed non-electric biopsy forceps using the same standard that MDUFMA imposes, i.e., whether the 510(k) exemption must be revoked in order to provide a reasonable assurance of safety and effectiveness, and concluded that revocation was not necessary.

Importantly, BSC, as well as AdvaMed and MDMA, make essentially the same arguments in their recent comments to FDA as BSC made in its 2001 Citizen Petition. Specifically they contend that the design of non-electric biopsy forceps makes them extremely difficult to clean and sterilize and that "studies" demonstrate reprocessed non-electric biopsy forceps pose a risk to public health.[9] FDA, however, flatly rejected these arguments in its denial of BSC's 2001 Citizen Petition:

> [T]he very studies you [BSC] submitted demonstrate that where QS requirements are met, the resulting reprocessed devices will present no unreasonable risk of harm. Although your studies suggest a lack of consistency in manufacturing by some reprocessors, they also demonstrate that it is possible for reprocessors to produce biopsy forceps that are clean and sterile. A reprocessor of a [single use device], just like a reprocessor of a device that an OEM markets for multiple use, can provide adequate sterilization. Indeed, your more recent studies of devices reprocessed by the same manufacturers show significant improvement in their ability to produce sterile devices. With proper process validation and monitoring of manufacturing, as required by the QS regulations, all non-electric G/U biopsy forceps coming off the reprocessing line should meet appropriate sterility specifications, as well as other performance specifications that you suggest may be compromised.[10]

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[8] Letter from Linda S. Kahan, Deputy Director for Regulations and Policy, CDRH, FDA to Beatrice Biebuyck, Esq., Boston Scientific Corporation at 2 (June 28, 2001) [hereinafter FDA Denial] (emphasis added).

[9] *See* Comments to MDUFMA docket from Anthony C. Bank, Corporate Regulatory Affairs, BSC, to FDA (Jan. 21 2003) [hereinafter BSC Comments]; Comments to MDUFMA docket from Tara Federici, Associate Vice President, AdvaMed to FDA (Feb. 7, 2003) [hereinafter AdvaMed Comments]; Comments to MDUFMA docket from Mark B. Leahey, Esq., Executive Director, MDMA (Jan. 23, 2003) [hereinafter MDMA Comments].

[10] FDA Denial, *supra* note 8, at 3-4 (internal citations omitted).

As in the initial BSC Citizen petition, the OEMs again attempt to portray FDA's 2000 Office of Science and Technology (OST) study, "Reprocessing Single Use Biopsy Forceps for Reuse,"[11] as evidence that non-electric biopsy forceps cannot be adequately sterilized.[12] Such characterizations gravely distort OST's actual findings. For example, MDMA asserts:

> In studies conducted by FDA's Office of Science and Technology using three types of single-use gastrointestinal biopsy forceps, researchers found that residual water remained in the devices following a typical cleaning sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse. This inability to dry adequately the device lumen decreases the effectiveness of sterilization. Thus, even when organic debris can be removed from these devices, the existence of residual water compromises the ability to sterilize them effectively.[13]

FDA clarified the actual nature of its findings in its denial of BSC's Citizen Petition:

> As you [BSC] acknowledge, CDRH's Office of Science and Technology determined through its own testing that biopsy forceps could be adequately cleaned. OST did not attempt to sterilize the devices, but it noted that if water remained in the lumen after cleaning, this might impede sterilization with EtO. This indicates that the manufacturing processes employed by reprocessors should ensure that the device lumen is dry prior to the sterilization step. The sterilization instructions provided with non-electric biopsy forceps designed for multiple use, which are exempt from 510(k), similarly instruct users to ensure that the lumen is dry before sterilization. Just as user instructions for multiple-use forceps help to ensure that a proper drying step is included in the user-sterilization process, quality system requirements and inspections will help ensure that reprocessors can produce sterile biopsy forceps by including an adequate drying step if appropriate.[14]

Another argument that was squarely rejected by FDA in its denial of BSC's Citizen Petition – but which the OEMs attempt to resurrect in their recent comments – is the notion that FDA's

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11 CDRH, "Reprocessing Single Use Biopsy Forceps for Reuse," Abstract for the 2000 FDA Science Forum from OST.

12 *See e.g.*, BSC Comments, *supra* note 9, at 5-6, 14; AdvaMed Comments, *supra* note 9, at 3.

13 MDMA Comments, *supra* note 9, at 2.

14 FDA Denial, *supra* note 8, at 4.

abandoned "Risk Prioritization Scheme" (RPS) in some way constitutes evidence that the 510(k) exemption for non-electric biopsy forceps should be revoked.[15] FDA introduced the RPS as part of a February 2000 draft guidance document, and subsequently discarded it because of concerns that it "lacked clarity and was too subjective."[16] As the agency stated in its denial of BSC's Citizen Petition:

> Your petition refers to the assessment of biopsy forceps as "high risk" reusable under a categorization approach found in FDA's draft guidance regarding the prioritization of enforcement against reprocessors. As you are aware, FDA abandoned the risk assessment categorization approach proposed in the draft guidance in light of comments demonstrating that it was arbitrary and unreliable, and that different persons applying the categories would achieve different results. Consequently, FDA no longer endorses the risk evaluations reported in the draft guidance.[17]

In sum, the question of whether non-electric biopsy forceps should retain their 510(k) exemption already has been carefully considered by FDA. The agency concluded that submission of a 510(k) "is not necessary to provide a reasonable assurance of safety and effectiveness and that devoting agency review resources to such submissions would not advance [our] public health mission."[18] Under MDUFMA, the agency is authorized to revoke an exemption only if submission of a 510(k) is necessary "in order to provide a reasonable assurance of the safety and effectiveness of the devices."[19] In their recent comments to FDA, the OEMs essentially have made the same arguments that FDA rejected in its denial of BSC's Citizen Petition. To the best of AMDR's knowledge, there is no credible new information that would justify FDA's now reversing the deliberative, science-based conclusions it reached in its denial of BSC's Citizen Petition. As such, AMDR strongly encourages FDA to refrain from revoking the 510(k) exemption for non-electric biopsy forceps.

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15 *See e.g.*, AdvaMed Comments, *supra* note 9, at 3-4; MDMA Comments, *supra* note 9, at 2; BSC Comments *supra* note 9, at 11.

16 FDA Guidance, *supra* note 4, at 4.

17 FDA Denial, *supra* note 8, at 2 (emphasis added).

18 *Id.*

19 MDUFMA § 302(b).

2. FDA Should Not Terminate the 510(k) Exemptions for Any Other Reprocessed Single Use Device.

In addition to recommending that FDA revoke the 510(k) exemption for non-electric biopsy forceps, the OEMs also ask the agency to terminate the exemption for a number of other devices. In AMDR's view, there exists no public health rationale for removing the exemption for any reprocessed single use device.

As a threshold matter, non-electric biopsy forceps arguably are the most challenging from a cleaning perspective of the 510(k)-exempt devices that AMDR companies reprocess. Given that FDA determined that a 510(k) is not necessary to provide a reasonable assurance of safety and effectiveness for this product, it is difficult to imagine how the agency could reach a different conclusion for less challenging devices, e.g., simple stainless steel devices such as surgical burrs and blades, which are extremely easy to clean and sterilize.

Significantly, the OEMs' recommendations as to which products should lose their exemptions are based primarily on their own uninformed speculation about the ability of certain devices to be safely reprocessed. For example, AdvaMed states that "ENT burrs/blades cannot be effectively cleaned, resulting in tissue and other residues inside the device."[20] As a practical matter, OEMs cannot be regarded as experts on the "reprocessability" of devices that they choose to label as "single use." To the contrary, OEMs have a strong economic motivation to promote the notion that "single use" devices cannot be safely reprocessed, as this potentially will discourage hospitals from using reprocessed devices and ultimately could lead to a more burdensome regulatory framework for reprocessors.

What the OEMs have failed to do, however, is to present a credible public health rationale for why any currently exempt reprocessed "single use" device should lose its exemption. It is AMDR's position that no such public health rationale exists. As such, AMDR strongly urges FDA to preserve the 510(k) exemption for all currently exempt reprocessed single use devices.

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[20] AdvaMed Comments, *supra* note 9, at 2.

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

PJF:la
cc: Tim Ulatowski
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