1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

October 24, 2003

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

Re: Comments on Bundling Policy Docket No. 02N-0534, Medical Device User Fee and Modernization Act (MDUFMA)

Dear Sir or Madam:

AdvaMed submits this letter in response to the Food and Drug Administration's (FDA's) February 4, 2003 Federal Register notice soliciting comments on the issue of bundling medical device submissions.[1] Specifically, we are responding to the August 8, 2003 comments submitted by the Association of Medical Device Reprocessors (AMDR) which attempt to persuade the FDA that reprocessors of single use devices should be permitted to bundle devices manufactured from multiple original equipment manufacturers' (OEMs') underlying devices in a single 510(k) submission. It is our position that, in most instances, this should not be permitted.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members 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.

AdvaMed submitted a letter to FDA on January 22, 2003, responding to the FDA request for comments on the issue of bundling medical device applications into a single submission. In this letter, we stated that reprocessed devices should be handled in the same manner as original devices, with the caveat that a single submission should not seek clearance for reprocessed devices manufactured from more than one OEM's device.[2]

---

[1] See Medical Device User Fee and Modernization Act of 2002; Establishment of a Public Docket, 68 Fed. Reg. 5,643 (Feb. 4, 2003)

[2] See Comments from Carolyn D. Jones, Associate Vice President, Technology and Regulatory Affairs,

Prohibiting the bundling of devices made by different OEMs is necessary to ensure an accurate assessment of medical devices by FDA. Even for devices within the same general type of device, each OEM may use a unique design, materials, manufacturing processes, technology, and engineering processes to make its device. Each OEM is likely to use different patentable technologies to manufacture its devices, and, unless shown otherwise by the reprocessor, FDA should presume that these technological differences do not support bundling. The varying technological information is crucial in FDA's assessment of any 510(k) or PMR submission for reprocessing of disposable single use devices. If the different technologies and processes were all grouped together in a single premarket submission, the submission would either become unwieldy, or more likely, would fail to adequately describe each of the various devices it purports to cover. To effect a complete and accurate assessment of any proposal to reprocess a disposable single use device, FDA must be able to adequately review the critical design and manufacturing characteristics of *each device* as they relate to the safety and effectiveness of each reprocessed device. Therefore, it is improper to allow the bundling of devices from multiple OEMs in any premarket submission which seeks authorization to reprocess disposable single use devices. It is significant to note that this position is consistent with what FDA requires for OEMs: specifically, bundling is not appropriate where the devices involve different engineering processes or technologies.

AMDR also argues that since all of the devices are reprocessed in the same manner, they therefore present the same scientific and regulatory issues in a submission. However, this argument fails to recognize two critical factors. First, different OEMs' device models may react differently to the harsh agents often used to reprocess them, thereby affecting the device's performance.[3] The health risks associated with reprocessing single use devices may vary with each OEM's device model and manufacturing technology. Second, and perhaps more important, a reprocessor's 510(k) is not merely an application to approve the cleaning of an OEM device. If it were, FDA would not be permitted to clear any such 510(k) because it would result in misbranded devices sold in contravention of the single use only label. Instead, FDA has determined that a reprocessor 510(k) is a 510(k) for a new device manufactured by the reprocessor. As such, FDA must review all aspects of the device, not just its "cleanability", in the 510(k). Thus, even devices that could be cleaned by similar techniques cannot be bundled if some other aspect of their design is too disparate for bundling.

Finally, during the congressional discussions on the Medical Device User Fee and Modernization Act, we learned that under FDA's current practice of allowing the submission of a single 510(k) for reprocessed devices originally manufactured by multiple OEMs, one reprocessor was able to gain clearance for over 4,000 devices on the basis of only eleven 510(k)s. Any FDA policy that would allow an average of over 350 devices per 510(k) is overly broad and cannot lead to a proper review of devices. Further it is wholly inconsistent with the current legislative mandate that any 510(k) for a

---

AdvaMed, to FDA MDUFMA Docket 02N-0534 (January 22, 2003).

[3] AdvaMed does agree with ADMR's stated view that cleaning data is essential to the review of any 510(k) for a reprocessed single use device and encourages FDA to review such data.

reprocessed SUD must establish that each *final reprocessed device* is substantially equivalent to a legally marketed predicate device.

For the foregoing reasons, AdvaMed believes that FDA should declare it improper for reprocessors to bundle devices made from different OEMs into a single FDA submission.

Sincerely,

Tara Federici

Tara Federici
Associate Vice President
Technology and Regulatory Affairs