AMDR
Association of Medical Device Reprocessors

1483 '03 AUG -8 P2:56

August 8, 2003

BY HAND DELIVERY

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

Re: Docket No. 02N-0534; Comment on Bundling Policy

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the February 4, 2003 publication by the Food and Drug Administration (FDA) of a *Federal Register* notice soliciting input on the agency's policy regarding bundling.[1] AMDR is a Washington, D.C.-based trade association representing the legal and regulatory interests of third-party reprocessors of medical devices originally labeled for "single use,"[2] and these comments, therefore, focus on the issue of bundling as it pertains to reprocessed devices.

For the reasons set forth below, AMDR supports the current FDA practice of allowing the submission of a single premarket review submission for reprocessed devices originally manufactured by multiple original equipment manufacturers (OEMs), where the devices are of the same generic type. This practice allows for the efficient review of the similar regulatory and technical issues that are presented by the reprocessing of these devices.

---

1 *See Medical Device User Fee and Modernization Act of 2002; Establishment of a Public Docket,* 68 Fed. Reg. 5643 (Feb. 4, 2003). In a letter to Congress regarding performance goals pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), FDA stated its intention to examine the issue of bundling. *Performance Goals for the Medical Device User Fee and Modernization Act of 2002*, Cong. Rec. S11549, 11550 (daily ed. November 19, 2002).

2 It is estimated that AMDR members perform approximately 95% of the third-party reprocessing done in the United States.

02N-0534 C 39

Office 1400 16th Street NW, Suite 400 Washington, DC 20036 **Phone** (202) 518-6796 **Fax** (202) 234-0399 **Web** www.amdr.org

FDA defines "bundling" as "the inclusion of multiple devices, or multiple indications for use for one device, in a single premarket submission."[3] Bundling is permitted for different models within a generic type of device or for devices that are of different generic types,[4] where the devices "present scientific and regulatory issues that can most efficiently be addressed during the course of one agency review."[5]

AMDR's comments are confined to the bundling in a single application of different models within a generic type. A "generic type of device" is defined by regulation as "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness."[6]

OEMs have argued that, while they should be permitted to bundle different versions of a generic type of device manufactured by a single OEM, reprocessors should not be permitted to bundle different versions of a generic type of device manufactured by different OEMs.[7] AMDR urges FDA to reject this approach to bundling.

---

3 *Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA*, available at http://www.fda.gov/cdrh/mdufma/guidance/1201.pdf ("FDA Guidance").

4 *Id.*

5 *Id.* at 9.

6 21 C.F.R. § 860.4(i).

7 *See, e.g.* Comments from Carolyn D. Jones, Associate Vice President, Technology and Regulatory Affairs, AdvaMed, to FDA MDUFMA Docket 3-4 (January 22, 2003).

Permitting reprocessors to bundle multiple devices that were manufactured by different OEMs but that are of the "same generic type of device" is consistent with FDA's rationale for its bundling policy. Reprocessing a device labeled for "single-use" entails cleaning, testing, and sterilization. The protocols developed for these processes with respect to multiple versions of a generic type of device are extremely similar, if not identical.[8] In other words, submissions for reprocessing of devices that are of the same generic type, but manufactured by different OEMs, generally present scientific and regulatory issues that can most efficiently be addressed during the course of one agency review. As such, bundling of such devices within a single submission should be permitted.

Despite the clear efficiencies bundling provides to both the agency and to the reprocessing industry, OEMs oppose it, arguing that bundling of reprocessed devices poses risks to the public health. They have, however, provided no evidence of such harm. In fact, no such evidence exists. To the contrary, bundling benefits public health because it speeds reprocessed devices to the market, allowing hospitals quicker access to safe, lower-cost medical devices. The money saved helps hospitals – which are under enormous cost-containment pressures – to continue to provide health care to the communities they serve. Thus, speedy access to safe reprocessed devices *benefits* the public in a variety of tangible ways, by freeing hospital resources for such things as the purchase of new equipment, the development of new expertise, and the improvement in health care access for indigent populations. Permitting bundling of reprocessed device submissions also benefits the public health by freeing FDA's resources for the review of *other* submissions, resulting in faster market entry for new health care technologies.

In conclusion, AMDR supports the current FDA policy of allowing the submission of a single premarket submission for reprocessed devices from multiple OEMs, where the devices are of the same generic type, presenting similar regulatory and technical issues that can efficiently be reviewed concurrently. Requiring individual submissions for the reprocessing of each model or version of a generic type of device would have a negative impact on agency efficiency without any corresponding public health benefit.

---

[8] Examples of devices for which the cleaning, testing, and sterilization protocols are extremely similar, if not identical, are gastrointestinal biopsy forceps (electric and non-electric); orthopedic burrs, bits and blades; arthroscopic shavers; electrophysiology catheters; external fixation devices; laparoscopic instruments; and PHACO needles.

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,

Pamela J. Furman, Esq.
Executive Director

PJF:la
cc: Daniel Schultz (by telecopy)
Timothy Ulatowski (by telecopy)
Barbara Zimmerman (by telecopy)
Lily Ng (by telecopy)