

ATTACHMENT F



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Nancy Singer, Esq.
Special Counsel
Health Industry Manufacturers Association
1200 G Street, N.W., Suite 400
Washington, D.C. 20005

Docket No. 97P-0377

Dear Ms. Singer:

This letter is in response to your citizen petition on behalf of the Health Industry Manufacturers Association (HIMA), dated September 5, 1997, to require commercial ("for profit") reproprocessors of disposable medical devices to comply with all applicable FDA regulations governing medical device manufacturing, including premarket notification (510(k)), premarket approval (PMA), medical device reporting (MDR), device labeling, good manufacturing practices (GMPs), establishment registration, and device listing. The petition states that it does not apply to reproprocessors of disposable hemodialyzers or end-user facilities, i.e., hospitals, clinics, etc. A response to the HIMA petition, filed in the Dockets Management Branch by the Association for Medical Device Reprocessors (AMDR), will also be addressed in this letter. Thank you for the detailed petition and the important issues you raised. We regret the delay in responding.

The petition requests that commercial reproprocessors be required to comply with the GMPs. This is already the case. These reproprocessors 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. The letter states that "any person or firm that reprocesses medical devices for health care facilities and engages in repackaging, relabeling, or sterilization activities (including any associated processing operations, e.g., cleaning) are required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal regulations, 21 CFR Parts 820 and 801, respectively." 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 which became effective in June 1997 (with a special 1 year transition period for design control compliance). Inspections have been conducted of several such facilities and follow-up regulatory action has been taken, as

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appropriate, including the issuance of Warning Letters. Assignments to inspect previously uninspected reprocessors will also be issued.

FDA believes that reprocessors' and original equipment manufacturers' (OEMs') compliance with GMP requirements provides an appropriate measure of public health protection for patients and health care providers by ensuring sufficient control over the individual firm's manufacturing and quality assurance operations. These requirements provide a reasonable assurance that the firm is providing devices that meet appropriate specifications for safety and performance. In addition, reprocessors are also subject to medical device reporting, registration, and listing requirements. FDA notes the current general absence of evidence of adverse patient outcomes attributed to the reuse of single-use devices.

The Association of Medical Device Reprocessors (AMDR) submitted a March 12, 1998, response to the HIMA citizen petition requesting denial of that petition, while raising legal questions of FDA's statutory authority to require device marketing clearance for reprocessing devices. Our reply to your petition will not respond to AMDR's legal argument except to note that FDA's regulatory approach is not based on their legal position. Rather, FDA will continue to rely on labeling and existing postmarket requirements, which include relevant GMP requirements, medical device reporting, registration and listing, and labeling.

FDA is very interested in learning the effects that reprocessed devices have on patients. An FDA laboratory project is currently evaluating the effects that various cleaning agents have on device performance, and the material composition of used balloon angioplasty catheters. This project aims to establish how the reprocessing of the used devices could affect device utility. Additionally, we are encouraging trade and scientific organizations, OEMs, user facilities, and others, to provide any data demonstrating adverse patient outcomes from the use of reprocessed "single use only" devices. We encourage HIMA to provide any such data to FDA for our review. To date, FDA has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes.

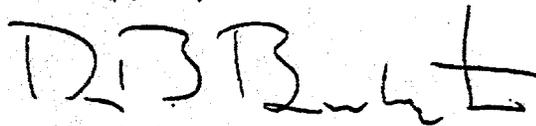
Finally, FDA published an Advanced Notice of Proposed Rulemaking (ANPRM) in the Federal Register of December 23, 1997 (62 FR 67011), regarding device refurbishers, reconditioners, servicers, and as-is remarketers. The public comment period was extended to June 29, 1998. The ANPRM focuses primarily on capital equipment; however, the ANPRM may be used as a venue to provide an opportunity to comment on FDA's regulation of reprocessed single-use devices.

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Until the agency has an opportunity to review and evaluate any comments concerning this issue, it is premature for the agency to make any decision regarding a change in FDA's regulatory position.

Once again, we appreciate receiving your citizen petition on this most important subject. If you have any questions, please contact Mr. Larry Spears at 301-594-4646, Ext. 151.

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. B. Burlington". The signature is written in a cursive, somewhat stylized font.

D. Bruce Burlington, M.D.

Director

Center for Devices and
Radiological Health