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January 27, 2000

Dockets Management Branch (HFA-305)  
Docket No. 99N-4491  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dear Sir/Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) proposed strategy for reuse of single-use devices. The Medical Waste Institute (MWI) understands that the issues raised during the December 14 meeting and in the strategy itself are broad; however, our comments are focused on single-use sharps containers only. While not specifically mentioned in the strategy, MWI knows that sharps containers are devices within FDA's rules and according to Larry D. Spears, Director, Division of Enforcement III, Office of Compliance, CDRH, are included in the strategy.

MWI is comprised of over seventy member entities that conduct business across all fifty states. These entities transport, treat, handle, dispose of, and otherwise manage medical, hospital, infectious, and chemotherapeutic waste materials. They also consist of manufacturers of products and equipment used in the medical waste business, including the manufacture of the sharps containers subject to FDA rules.

MWI is a component of the Environmental Industry Associations, a non-profit trade association representing some 2,000 private waste service and manufacturing businesses. These firms collect solid and hazardous wastes, including medical waste; own and operate landfills; collect and process recyclable materials from residential and commercial establishments; provide consulting and legal services to waste management entities; and manufacture products and equipment used in these businesses.

In reviewing the proposed strategy, FDA clearly stated that the agency was concerned about the adverse health risks to patients associated with the reuse of single-use devices. The reuse of single-use sharps containers also poses a risk to employees of facility environmental service

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departments, transporters of medical waste, and waste handlers at treatment and disposal facilities.

Specifically, MWI has two concerns with FDA's proposed strategy as applied to single-use sharps containers. First, the strategy does not sufficiently address worker safety. Second, the proposed strategy does not address the issue of jurisdiction with other federal agencies, which at best is overlapping.

To protect employees and patients, MWI recommends that the reuse of single-use sharps containers only be allowed if the containers can be rehabilitated or reprocessed to their original manufactured quality. While MWI understands the desire to save money and reuse or recycle single-use sharps containers, the additional handling required to reuse these containers creates a health risk that is avoidable. The generator facility may save a few dollars, but healthcare workers, housekeepers, regulated medical waste management facility employees, transportation personnel, and patients and their families are all placed at risk. Specifically, bloodborne pathogen risks increase once these sharps containers are opened. A facility that prefers reusables should purchase multiple-use sharps containers. These multiple-use sharps containers are readily available on the market and are designed to prevent worker injury.

Perhaps more importantly, MWI is concerned about whether the reuse of single-use sharps containers will meet U.S. Occupational Safety and Health (OSHA) and U.S. Department of Transportation (DOT) regulations. To reuse single-use sharps containers requires workers to open lids not designed for reopening; therefore, the potential for needlestick injuries increases. We believe this may be a violation of OSHA's Bloodborne Pathogens Standard and new compliance directive, OSHA Instruction CPL 2-2.44D. In addition, under OSHA regulations, a container can only be reopened through an automated process. This process may damage containers not designed to be reopened; thus, restoring the containers to their original manufactured quality may not be possible.

Currently, there is insufficient data to show whether the resealing of single-use sharps containers will prevent leakage during transport, a violation of DOT rules. In fact, if the FDA allows the reuse of single-use sharps containers, there could be a direct conflict with DOT rules. An original manufacturer may place on a single-use sharps container a permanent marking that the container meets DOT requirements. This marking is required when cultures and stocks are being transported and for transporters that are not private or contract carriers using vehicles dedicated to the transport of infectious substances. The marking will still

be on the containers after "reprocessing" even though the containers have not undergone retesting. Therefore, the "reprocessed" containers will show that the containers comply with DOT rules when, in fact, they may not. MWI understands that FDA is considering labeling requirements, but these labels may conflict with DOT labeling rules.

MWI hopes that FDA will not jeopardize compliance with other federal agency rules or allow for unsafe working conditions. Therefore, we request that FDA work closely with OSHA and DOT before issuing any final strategy.

MWI members would like to meet with the FDA to assist the agency in developing a final strategy and in making appropriate contacts with other agencies. If you have any questions, please contact me at 202-364-3724 or [alicej@envasns.org](mailto:alicej@envasns.org).

Sincerely,



Alice P. Jacobsohn  
Senior Manager, Waste Programs and Research

cc: Thomas P. Herbert (MWI Chairperson)  
Larry D. Spears, CDRH, FDA

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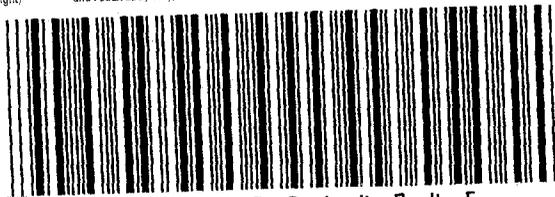
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