

**From:** Snesko, Walter M. [WMS@CDRH.FDA.GOV]  
**Sent:** Tuesday, June 14, 2005 3:22 PM  
**To:** 'Garywayyn@aol.com'  
**Subject:** RE: Sure-Way's referbisher letter

Dear Mr. Chilcott,

Sharps Containers are medical devices, the firm(s) that services medical devices without changing the medical devices original specifications or performs cosmetic work on the device, prior to the device re-entering commerce, is considered a refurbisher. The Food and Drug Administration does not actively regulate refurbishers of medical devices.

Sincerely yours,

**Walter Snesko**

Division of Small Manufacturers, International and  
Consumers Assistance,  
Office of Communication, Education and Radiation  
Programs

Center for Devices and Radiological Health

Phone: 301-443-6597, ext 120 or 1-800-638-2041

FAX: 301-443-8818

E-mail: WMS@CDRH.FDA.GOV

<http://www.fda.gov/cdrh>

Thank you

Your 100% satisfaction is our #1 goal and your feedback is important to us.

If for any reason you are not completely satisfied or have a comment to make, please contact us toll-free at 1-800-638-2041, ext 136 or email us at : [dsmica@cdrh.fda.gov](mailto:dsmica@cdrh.fda.gov).

This response represents to the best of my judgment how the device should be regulated, solely based upon a review of the information you have provided. This response is not a classification decision for your device and does not constitute FDA clearance or approval for commercial distribution. Unless exempt from premarket notification submission (510(k)) requirements, the official classification for your device will appear on the final decision letter from any premarket review. All device types classified as exempt from the 510(k) requirements are subject to the limitations of exemptions. Limitations of device exemptions are found in the device classification chapters in 21 CFR xxx.9, where xxx refers to Parts 862-892 (e.g., 862.9, 864.9, etc.). Please be aware, if I have indicated that I believe your device falls within a device category classified as exempt from premarket review requirements, that it is your responsibility to ensure that you meet the exemption criteria and your device does not exceed the limitations of exemption. If your device exceeds the limitations of exemption, you must submit a 510(k) and receive a letter from FDA stating that your device may be commercially distributed in the U.S. prior to marketing your device.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

**From:** Garywayyn@aol.com [mailto:Garywayyn@aol.com]  
**Sent:** Tuesday, June 14, 2005 4:04 PM  
**To:** wms@cdrh.fda.gov  
**Cc:** GHW@curranmendoza.com  
**Subject:** Sure-Way's referbisher letter

June 14, 2005

Walter Sesnusko, FDA  
800-638-2041

Walter

Thank you so much for setting me straight. Sure-Way as a refurbisher is sure makes sense!

Sure-Way is simply washing its own sharps containers had them built with their molds and not changing the specifications they qualifies as a referbisher because they are not changing the specifications

PLEASE send me a letter confirming our conversation today that our plants that robotically empty and wash/sanitize our sharps containers are a referbishing process and not a remanufacturing process that would require our plants that do the tipping/sanitizing of the containers register with the FDA, since we are the owners of the molds and have them manufactured for us to our specifications as laid out under our FDA authorization K992626 and QSR

The trade name Sure-Way Reusable Sharps Container

Walter if you could "E" mail me a copy and send me an original I sure would appreciate it  
Thanks again

**Gary Chilcott, Pres./C.E.O.**

Sure-Way Systems, Inc.  
208 Missouri Ave.  
Deer Lodge, MT 59722  
800-822-3929  
Cell 406-490-9768