



9/28/00

REPROCESSING OF
SINGLE-USE DEVICES

To: Risk Management
Hospital Administration
Central Supply
Infection Control Departments
Safety Office
Operating Room
Medical Department
Nursing Department
(Please make copies for relevant departments.)

This is to advise you that on August 14, 2000, the U.S. Food and Drug Administration (FDA) released its final guidance on the practice of reprocessing and reusing medical devices that are intended to be used only once. In the enclosed guidance document entitled "[Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals](#)," FDA states that hospitals and third parties that reprocess single-use devices (SUDs) will be regulated in the same way as original equipment manufacturers. This means that hospitals reprocessing SUDs are subject to the requirements of the Food, Drug, and Cosmetic Act, including:

- registration and listing;
- good manufacturing practice (GMP) under the Quality System (QS) regulation;
- submission of adverse-event reports under the Medical Device Reporting (MDR) regulation;
- medical device labeling;
- medical device tracking;
- corrections and removals; and
- premarket notification and approval.

The goal of the SUD reuse policy is to protect the health of the public by ensuring that the practice of reprocessing and reusing SUDs is based on good science and that the regulatory requirements are equitable to all parties (i.e., third-party and hospital reprocessors and original device manufacturers).

The major points of the reuse policy for hospital reprocessors are:

- FDA intends to enforce **premarket submission requirements** by:
 - **February 14, 2001**, for all class III devices;
 - **August 14, 2001**, for all non-exempt class II devices; and
 - **February 14, 2002**, for all non-exempt class I devices.

These enforcement priorities are based on a device's classification (i.e., class I, class II, or class III) as listed in the *Code of Federal Regulations* (CFR).

- FDA intends to enforce the **non-premarket requirements** (i.e., registration and listing, the QS regulation, medical device reporting, labeling, tracking, and corrections and removals) by **August 14, 2001**. FDA will use the one-year period to educate hospitals about their regulatory obligations if they reprocess SUDs.

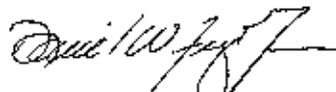
The Agency encourages hospitals to pay particular attention at this time to the regulatory requirements for Good Manufacturing Practices (www.fda.gov/cdrh/dsma/cgmphome.html). Any hospital that intends to continue reusing and reprocessing SUDs will need to understand these requirements, which include process validation, corrective and preventive action, quality system inspection, and controls used for packaging, labeling, storage, installation, and servicing of all reprocessed SUDs.

- FDA has developed a list of known reprocessed SUDs that range from technically simple to complex devices. (See [Appendix A](#) of the guidance document.) **Although many SUDs are exempt from some of the regulatory requirements, all reprocessed SUDs are still subject to the GMP requirements of the QS regulation.**
- The SUD enforcement priorities **do not apply** to:
 - permanently implantable pacemakers;
 - “open-but-unused” single-use devices;
 - health care facilities that are not hospitals; and
 - hemodialyzers. The reuse of hemodialyzers is addressed in “Guidance for Hemodialyzer Reuse Labeling” (October 6, 1995) and is available at www.fda.gov/cdrh/ode/dilreuse.pdf.

Nothing in the guidance document precludes FDA from taking immediate action against any device that is causing harm.

Please read the enclosed guidance document. It is important that you become familiar with it in order to understand your hospital’s responsibilities. Hopefully, this information will assist you as you evaluate your SUD reprocessing program with the goal of promoting and enhancing patient safety. To further assist you, we have attached the names of several sources that have listings of medical device consultants. If you have any questions or need additional information, contact us at our e-mail address reuse@cdhr.fda.gov or at FAX number 301-443-8818.

Sincerely yours,



David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health

Attachment: Sources of Medical Device Consultants
Enclosure: [SUD Enforcement Priorities Guidance](#)

Attachment

SOURCES OF
MEDICAL DEVICE CONSULTANTS

The following sources provide lists of medical device consultants who can provide assistance with meeting the regulatory requirements [such as 510(k) and PMA] of the FD&C Act.

Food and Drug Law Institute (FDLI)
1000 Vermont Avenue, NW, Suite 200
Washington, DC 20005
<http://www.fdi.org>

Cannon Communications
<http://www.devicelink.com/consult>

Regulatory Affairs Professional Society (RAPS)
11300 Rockville Pike, Suite 1000
Rockville, MD 20852
<http://www.raps.org/memb/yellow.cfm>

Periodically, check our Reuse Homepage at <http://www.fda.gov/cdrh/reuse/index.shtml> for additions to the above sources and other important information.