DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Enforcement of FDA Requirements on Reprocessing of Single-Use Devices

(You are encouraged to copy and distribute this information.)

April 23, 2001

Dear Hospital Administrator and Hospital Risk Manager:

On several occasions over the past few months, we have notified hospitals about our intention to enforce certain requirements regarding the reprocessing of single-use medical devices (SUDs) for later use on patients. We are taking this action because of public health concerns about the cleaning, disinfecting, and sterilizing of previously used SUDs, and the effect reprocessing may have on the functional integrity of the reused device**.**

In brief, we will now require hospitals that reprocess SUDs to meet the same regulatory requirements as the original manufacturer of the product. We will enforce these requirements for hospitals just as we do for medical device manufacturers.

This letter is to remind hospitals that reprocess SUDs about our requirements, to provide a timetable of when we intend to begin enforcing them, and to inform you of actions we may take against hospitals that do not comply with them. Hospitals that do not reprocess SUDs are not affected by any of the actions described in this letter.

Regulatory requirements for SUD hospital reprocessors

As a device manufacturer, a hospital that reprocesses SUDs is required to comply with seven requirements of the Federal Food, Drug and Cosmetic Act (the Act), which are summarized on pages 12 through 25 of the guidance document enclosed with this letter. It is essential that hospitals wishing to continue the reprocessing of SUDs comply with these regulations in order to avoid FDA enforcement action. *Please note that all SUD hospital reprocessors are subject to inspections of their facilities by FDA investigators, whether or not these devices are subject to the premarket submission requirements of the Act.*

Enforcement timetable

Until now, we have not enforced the regulatory requirements that apply to SUD hospital reprocessors. Our enforcement guidance sets forth certain dates when FDA intends to

start actively enforcing these requirements. There are several important dates that SUD hospital reprocessors should be aware of:

February 14, 2001:

Deadline for the submission of premarket approval (PMA) applications or premarket notifications (510(k)s) for class III SUDs. (Note that the class for each device known to be reprocessed is given in Appendix A, pages 32 through 39, in the enclosed guidance document.) After that date, we intend to start enforcing the premarket requirements for reprocessed class III SUDs that do not have a PMA or 510(k) on file. Further, if the hospital reprocessor has not obtained an FDA marketing approval order or clearance by August 14, 2001, we will take enforcement action if the reprocessing practice continues.

August 14, 2001:

Deadline for hospital reprocessors to comply with (a) non-premarket requirements for class I, II, and III devices, as described in the enclosed guidance document, and (b) premarket requirements for the submission of 510(k)s for any class II SUD, unless the classification regulation specifically exempts the device. After that date, we intend to start enforcing the non-premarket requirements for all reprocessed SUDs that do not comply with these two requirements. Further, if the hospital reprocessor has not obtained an FDA marketing clearance order by February 14, 2002, we will take enforcement action if the reprocessing practice continues.

February 14, 2002:

Deadline for the submission of 510(k)s for any class I SUD, unless the classification regulation specifically exempts the device. After this date, we intend to start enforcing our premarket notification requirements for reprocessed class I SUDs that do not have a premarket notification on file. Further, if the hospital reprocessor has not obtained an FDA marketing clearance order by August 14, 2002, we will take enforcement action if the reprocessing practice continues.

Regulatory actions FDA may take against non-compliant hospitals

Under the Act, we are authorized to take any of the following regulatory actions against a non-compliant device manufacturer (in this case, a hospital):

1. Public health alerts and notifications. We have the authority to require a hospital to directly notify health care providers, consumers, and other relevant parties of devices that pose actual or potential risk to the health of the public. In addition, we have the authority to issue our own alerts and notifications on issues that are of a public health concern.

2. Warning Letter. This is an official FDA document that would inform an individual hospital that we have found serious violations of the Act, and that we may initiate

action without further notice if the violations are not promptly corrected. However, we are not legally obligated to send a Warning Letter prior to initiating action.

3. Mandatory recall. We have the authority to require a hospital to recall a reprocessed SUD if it could cause serious, adverse health consequences or death.

4. Seizure. We have the authority to seize a medical device that we consider to be adulterated (e.g., one that is determined not to be in compliance with the quality system requirements) or misbranded (e.g., one that is labeled with an incorrect device description, such as size).

5. Injunction. We may seek an injunction against a hospital to prevent manufacturing or distributing a device that violates a requirement of the Act.

6. Civil money penalties. We may initiate an administrative proceeding to impose civil money penalties of up to $1 million (per proceeding) against persons who violate the Act.

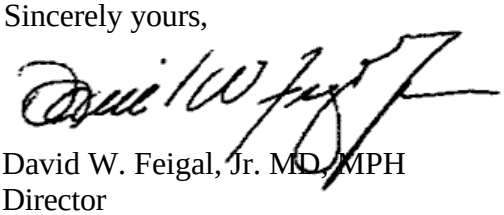
7. Prosecution. We have the authority to initiate action to criminally prosecute persons responsible for violations of the Act.

Recommendations

We recommend that you familiarize yourself with FDA's reprocessing and reuse policy if you intend to engage in or continue in these manufacturing activities. We encourage you to explore our Internet site for information and guidances on the SUD reuse issue (www.fda.gov/cdrh/reuse). In particular, please consult the enclosed guidance document, which sets forth our policy on how we intend to regulate hospitals that reprocess SUDs, as well as our priorities for enforcing these requirements. We also encourage you to consult with our Division of Small Manufacturers Assistance (DSMA) by calling 1-800-638-2041 or e-mailing DSMA at DSMA@CDRH.fda.gov.

We realize that these regulations are not familiar to most hospitals, and that compliance with them will not be easy. But we must enforce them for the sake of patient safety. Our goal - and yours, I am sure - is to see to it that patients who receive reprocessed SUDs are afforded the same level of safety and effectiveness as those who receive new ones.

Sincerely yours,



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Center for Devices and Radiological Health

Enclosure

Suggested Reading

The following is a partial list of guidances and material that may be helpful to you. Copies of the guidances can be obtained from FDA's Internet site at www.fda.gov/opacom/morechoices/industry/guidedc.htm or by contacting the Division of Small Manufacturers Assistance by calling 301-443-6597 or 1-800-638-2041; by e-mailing DSMA@CDRH.fda.gov; or by faxing 301-443-8818. You also are encouraged to search the Device Advice web site at www.fda.gov/cdrh/devadvice for specific guidance to new manufacturers.

- Overview of FDA Modernization Act of 1997, Medical Device Provisions, February 19, 1998
- Quality System Inspection Technique (available at www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF)
- Medical Device Quality Systems Manual: A Small Entity Compliance Guide (available at www.fda.gov/cdrh/dsma/gmpman.html)
- Design Control Guidance for Medical Device Manufacturers (available at www.ghtf.org/sg3/sg3-final.html)
- Process Validation Guidance (available at www.ghtf.org/sg3/sg3-final.html)
- Guidance on Quality Systems For the Design and Manufacture of Medical Devices (available at www.ghtf.org/sg3/sg3-final.html)
- Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30. 1986
- Premarket Approval (PMA) Manual, October 1, 1988
- FDA Labeling Requirements at www.fda.gov/cdrh/devadvice/33.html#contents

Additional Copies of Guidance Document

Additional copies of the SUD enforcement guidance are available from the World Wide Web/CDRH home page: http://www.fda.gov/cdrh/reuse/index.shtml or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1168 when prompted for the document shelf number.