MEDICAL DEVICE REPORTING
FDA MEDICINE MANUFACTURERS

User Facility Reporting

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AUGUST 14, 2001: IMPORTANT ENFORCEMENT DATE FOR HOSPITAL REPROCESSORS OF SINGLE-USE DEVICES

In a letter to hospitals on April 23, 2001, David W. Feigal, Jr., M.D., M.P.H., Director of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health, wrote: "In brief, we will now require hospitals that reprocess SUDs [single-use devices] 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."

A copy of the guidance document, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, August 14, 2000 (http://www.fda.gov/cdrh/reuse/1168.html), also was enclosed. Dr. Feigal's letter gave a timetable of when FDA will begin enforcing the regulatory requirements and what actions FDA will take for non-compliant hospital SUD reprocessors. A copy of Dr. Feigal's letter is available from the Internet at http://www.fda.gov/cdrh/reuse/042301_reuse.pdf.

Enforcement Timetable

February 14, 2001:

Deadline for the submission of premarket approval (PMA) applications or premarket notification (510(k)) submissions for class III SUDs. After that date, FDA will start enforcing the premarket notification requirements for reprocessed class III SUDs that do not have a PMA or 510(k) on file with FDA. (Note that the class for each device known to be reprocessed is given in Appendix A of the Enforcement Priorities guidance.) The hospital SUD reprocessor must have an FDA marketing approval or clearance order (that is, a PMA approval or a letter of substantial equivalence) by August 14, 2001, or FDA will take enforcement actions if the reprocessing practice continues.

August 14, 2001:

Deadline for hospital SUD reprocessors to comply with:

- non-premarket requirements for class I, II, and III devices, and
- premarket requirements for the submission of a 510(k) for any class II SUD, unless the classification regulation specifically exempts the device.

(See the articles that follow in this issue of the *Bulletin* for information about the regulatory requirements for reprocessed SUDs.)

The hospital SUD reprocessor must have an FDA marketing clearance by February 14, 2002, or FDA will take enforcement actions if the reprocessing practice continues.

February 14, 2002:

Deadline for the submission of a 510(k) for any class I SUD, unless the classification regulation specifically exempts the device. After this date, FDA intends to enforce the premarket notification requirements for reprocessed class I SUDs that do not have a premarket notification on file by August 14, 2002.

Regulatory Actions FDA May Take

Under the Federal Food, Drug, and Cosmetic Act (the Act), FDA is authorized to take any of the following

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regulatory actions for a non-compliant hospital reprocessor of SUDs:

- **Public Health Alert and Notification.** FDA has 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. FDA also may issue its own alerts and notifications on issues that are of public health concern.
- **Warning Letter.** This is an official FDA document that would inform an individual hospital that FDA has found serious violations of the act and may initiate action without further notice if the violations are not promptly corrected. FDA, however, is not legally obligated to send a Warning Letter **before** initiating action.
- **Mandatory Recall.** FDA has the authority to require a hospital to recall a reprocessed SUD if it could cause serious, adverse health consequences or death.
- **Seizure.** FDA has the authority to seize a medical device it considers adulterated (for example, a device determined not to be in compliance with the Quality System (QS) requirements) or misbranded (for example, one that is labeled with an incorrect device description such as size).
- **Injunction.** FDA may seek an injunction against a hospital to prevent the manufacturing or distributing of a device that violates a requirement of the act.
- **Civil Money Penalty.** FDA may initiate an administrative proceeding to impose civil money penalties of up to $1 million (per proceeding) against persons who violate the act.
- **Prosecution.** FDA has the authority to initiate action to criminally prosecute persons responsible for violations of the act.✿

Editor's Note: The articles in this issue of the *Bulletin* are related and should be read in sequence. They sound legalistic in tone because they are explanations of regulatory requirements. Some of the concepts, especially in the Quality System article, should be studied in detail for a complete understanding. The articles are meant as an overview, and the reader is directed to other sources for more detailed information of the various requirements.

PREMARKET NOTIFICATION

There are two types of premarket submissions: a premarket notification (510(k)) submission and a premarket approval (PMA) application. This article summarizes the requirements for a 510(k) submission.

The criteria that FDA uses in deciding to grant marketing clearance for a premarket notification submission are described in section 513(i) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 of the *Code of Federal Regulations* (CFR) Part 807 Subpart E. A premarket notification submission must include all of the information described in 21 CFR 807.87.

In general, the type of submission depends on the classification of the device. The classification regulation for a medical device, as provided in 21 CFR Parts 862-892, establishes the class for each type of device and the premarket requirements that are applicable. Unless the classification regulation specifically exempts a device, a premarket notification submission is required for class I and class II devices. Class III devices may require either a 510(k) submission or a PMA application. A list of SUDs known to be reprocessed is provided in Appendix A of the *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* available from the Food and Drug Administration's (FDA) Internet site at http://www.fda.gov/cdrh/reuse/1168.html).

A 510(k) submission for a reprocessed SUD must be submitted to FDA and contain enough information for FDA to determine whether the device is as safe and effective as a legally marketed predicate device,* that is, "substantially equivalent" within the meaning of section 513(i) of the Act. The hospital SUD reprocessor is responsible for identifying a legally marketed predicate device for the SUD it wishes to reprocess. For a reprocessed SUD, the legally marketed

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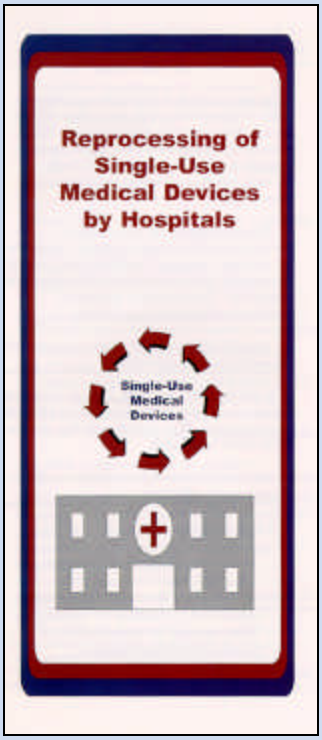

Get this brochure from the FDA Reuse website at: http://www.fda.gov/cdrh/reuse/trifold1.pdf or by sending an e-mail to dsma@cdrh.fda.gov or a FAX to 301-443-8818.

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predicate device for comparison may be the SUD of the original equipment manufacturer (OEM).

The SUD reprocessor must submit information in its 510(k) submission comparing the intended use and the characteristics of its device to a predicate device to establish that the devices are substantially equivalent with respect to safety and effectiveness factors. These factors may include design, sterility, biocompatability, strength of materials, and functionality. Information that addresses only the steps used in reprocessing a SUD would not be sufficient to receive marketing clearance.

For additional guidance on the 510(k) process, see the draft guidance of June 1, 2001, entitled *Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff* on the Internet at http://www.fda.gov/cdrh/ode/guidance/1331.pdf; *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* at http://www.fda.gov/cdrh/comp/guidance/1168.pdf; and the Device Advice website at http://www.fda.gov/cdrh/devadvice/51.html. The Reuse website also contains a variety of information relevant to reprocessing of SUDs (http://www.fda.gov/cdrh/reuse/ index.shtml). ✿

*A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process. (§807.92(3))

PREMARKET APPROVAL

As of February 14, 2001, hospitals that reprocess class III single-use devices (SUDs) for reuse in humans are required to submit premarket approval (PMA) applications to the Food and Drug Administration (FDA). Class III devices are those medical devices generally considered to pose the greatest potential risk to the health of the public and require the most regulation. Three examples of class III devices are:

- percutaneous transluminal coronary angioplasty (PTCA) catheters,
- implanted programmable infusion pumps, and
- endotracheal tube changers.

FDA's basis for approval of a PMA application is a finding that the device has a reasonable assurance of safety and effectiveness for its intended use based on valid scientific evidence. Clinical data may be necessary to establish the safety and effectiveness of a reprocessed SUD. The PMA application also should evaluate the unique characteristics of the reprocessed SUD. A description of what FDA considers a complete PMA application is given in the PMA regulation (21 CFR 814.20).

FDA has general guidance on the required information in a PMA application; see *Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff* at http://www.fda.gov/cdrh/ode/guidance/1331.pdf; *Premaket Approval Manual* at http://www.fda.gov/cdrh/manual/pmamanul.pdf; *Guidance for Preparation of PMA Manufacturing Information* at http://www.fda.gov/cdrh/ode/448.pdf.

Additional guidance is available from the Center for Devices and Radiological's (CDRH) Internet site at: http://www.fda.gov/cdrh. Click on the *Topic Index* button and scroll down to the *Premarket Approval* heading. Also, you can find helpful information on *Device Advice*, CDRH's self-service site for medical device and radiation emitting product information. *Device Advice* is an interactive system for obtaining information concerning medical devices (http://www.fda.gov/cdrh/devadvice/11.html). ✿

ELECTRONIC NOTIFICATION FOR THE *USER FACILITY REPORTING BULLETIN* IS NOW AVAILABLE

If you would like to be notified electronically (via e-mail) when a new issue of the *User Facility Reporting Bulletin* is released, you can sign-up for our new List Service at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCDRHNew/listman.cfm

ESTABLISHMENT REGISTRATION AND MEDICAL DEVICE LISTING

by Blix Winston, M.P.A., M.S.

On August 14, 2000, the Food and Drug Administration (FDA) released a guidance document entitled *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (http://www.fda.gov/cdrh/reuse/1168.html). In the guidance, FDA stated that it intended to apply its regulatory authority to hospitals and third parties that reprocess medical devices labeled for single use only (commonly known as single-use devices or SUDs). Hospital and third-party reprocessors are now considered by FDA to be "manufacturers" and must conform to the same requirements applicable to all medical device manufacturers.

This article discusses two of the requirements: Initial Registration of Medical Device Establishment (registration), and Medical Device Listing (listing). Hospitals must comply with the registration and listing requirement by **August 14, 2001**.

Registration and listing requirements are contained in Title 21 of the *Code of Federal Regulations* (CFR), in Part 807, subpart B. Initial Registration of Medical Device Establishment (form FDA-2891) tells FDA where the facility is located. Device listing (form FDA-2892) tells FDA that the organization has "introduced the device into domestic commerce", that is, the reprocessed device is being sold or used. Confusion sometimes arises when someone wants to "register" a device with FDA. Registration applies only to the manufacturing facility, in this case a hospital or third-party reprocessor, not to the device being reprocessed.

The FDA-2891 and FDA-2892 are single-page forms, each having multiple copies. They must be submitted together. **A registration form submitted by itself will be returned if unaccompanied by a listing form.** It will take the "Official Correspondent" (that is, the person responsible for submitting and maintaining the registration and listing information for the facility) about 10 minutes to complete each form. A hospital group will have to complete a registration form for each of its facilities. For example, a hospital chain managed under one organization will have a separate registration for each of its hospitals that reprocesses SUDs. The corporate office will be entered on the registration form as the "Owner/Operator." Similarly, a third-party reprocessing organization with facilities in several states will have one Owner/Operator and several registering facilities. The registration form includes information about the company such as name, address, and telephone number.

Submit separate listing forms for each device "type" reprocessed. A device "type" may include several models (for example, various types of reprocessed surgical blades). The device listing form includes information about the Owner/Operator, company name, classification name, and number for the device.

How does the Official Correspondent determine the “type” or classification for the devices being reprocessed? There are several methods. Since the original manufacturer has already listed the device, the listing database on the FDA/CDRH Internet site can be used to find the required classification information. You can search the listing database at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm by proprietary (brand) name, manufacturer name, the three-letter product code, and so on. For example, if the reprocessed device is an oximeter, enter the manufacturer name in the Owner/Operator block and click on *search*. Selecting the icon for the matching record will display the listed product along with the classification name and the three-letter product code ("DQA" in this example). When completing form FDA-2892, note that the product code is also the classification number required in block 8 on the listing form.

If you cannot easily find the information in the listing database, search the classification database. On the listing search screen, simply click on the blue "classification" tab at the top of the page. For our example, enter the word *oximeter* in the device name block in the classification search screen and click on *search*. The next screen will display 6 types of oximeters. To find cleared marketing applications for *DQA*, *oximeter*, move to the 510(k) database by clicking on that tab, and enter *DQA* in the product code box. Clicking *search* will pull up all the Premarket Notification applications (PNAs), also called 510(k)s, cleared by FDA.

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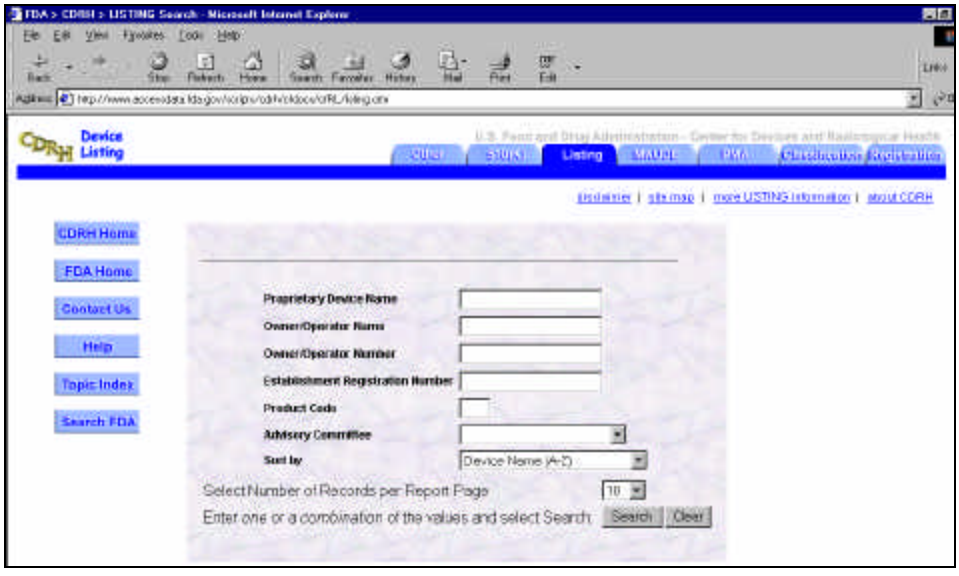

Device Listing Database

ESTABLISHMENT REGISTRATION - *From Page 4*

How to Obtain the Forms and Instructions

Send a fax to 301-443-8818, Attention: Publications. Request the number of registration and listing forms and the instructions needed. Include your name, address, and phone number. Alternatively, order the forms via e-mail to: gwa@cdrh.fda.gov. To view the registration and listing forms and instructions on-line, go to: http://www.fda.gov/cdrh/dsma/rlman.html.

The registration form can be downloaded from the webpage and submitted in **triplicate** to FDA. Keep a photocopy for your records and remember to include your listing form at the same time. FDA will assign your registration number after you submit the forms. You are registered with FDA when your registration form (FDA 2891) is received. You will not, however, receive your registration number for about 8 weeks.

Original listing forms must be used since they are sequentially numbered. They cannot be downloaded off the website. You will not receive confirmation when your listing forms are recieved.

Additional registration and listing information can be found on the CDRH Internet site at http://www.fda.gov/cdrh by clicking on *Postmarket Issues*, then clicking on *Registration and Listing*.

Here are a few tips and suggestions.

- Make photocopies of the registration forms you submit, since it will take about 8 weeks to receive your validated registration form.
- FDA will not send you a copy of the completed listing form. Before mailing, tear off and keep the bottom, yellow copy for your records.
- Set up a file for registration and listing information and forms. After the initial registration, FDA will send each registered facility a form FDA-2891a, Semi-annual Registration of Device Establishment. This form must be reviewed for changes and sent back to FDA. File all forms and changes so they will not be lost or thrown out.
- Periodically check on-line your registration and listing information to make sure it is up-to-date. Unlike Establishment Registration, FDA does not send semi-annual listing updates. You must check your listings semi-annually to be sure all device types are listed. Note: listing numbers do not appear on the listing record in the FDA database.
- If you add or delete device types, you will need to submit a new FDA-2892 to update this information.
- Obtain a return receipt when you mail your forms. ✿

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APPLYING THE QUALITY SYSTEM REGULATION TO HOSPITALS THAT REPROCESS SUDs

by Kimberly Trautman, M.S. Biomedical Engineer

A hospital that reprocesses a single-use device (SUD) for reuse must meet the current Quality System (QS) regulation for medical devices (Title 21of the *Code of Federal Regulations* (CFR) Part 820), unless the device is exempt from the Good Manufacturing Practice (GMP) requirements by the classification regulation. The QS regulation covers the methods, facilities, and controls used in design, manufacturing, packaging, storing, and installing medical devices. Also, the QS regulation requires that every manufacturer, including hospitals that reprocesses SUDs, prepare and implement a quality assurance (QA) program or quality system. This quality system must meet the requirements of the QS regulation. The Food and Drug Administration (FDA) monitors compliance with the QS regulation during inspection of a facility. All hospitals that reprocess SUDs are subject to periodic FDA inspection.

Regulatory requirements under the QS regulation are intended to assure that quality is continually incorporated into the devices during reprocessing, rather than removing defective devices after testing to achieve quality. That is, if all the steps or processes carried out during reprocessing are done properly, the final product should be safe and effective. This is done in addition to certain testing of products before distribution. For more information about current GMP under the QS regulation, visit FDA's Internet site at http://www.fda.gov/cdrh/dsma/cgmphome.html.

A hospital that reprocesses a SUD for reuse is considered to be a remanufacturer as defined in the QS regulation under 21 CFR 820.3(w). Remanufacturers of SUDs produce a finished medical device that has a different intended use -- that of more than one use. Further, they are manufacturers of a process (or processes) that takes a used medical device and processes it to meet the original specifications, thus allowing it to be used again. The hospital SUD reprocessor is responsible for designing such a process under the design control requirements specified in 21 CFR 820.30, as well as complying with the other requirements in 21 CFR 820 in order to carry out such processing.

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QS REGULATION - ***From Page 5***

"The documentation necessary to meet the requirements of the QS regulation may vary with the complexity of the design and manufacturing operations, the size of the firm or facility, the importance of a process, and the risks associated with failure of the device."

The QS regulation provides the "basic" requirements for the design and manufacture of medical devices. The requirements are written in general terms to allow manufacturers, including hospital SUD reprocessors, to establish procedures appropriate for their devices and operations. They need only comply with those requirements applicable to their operations. However, because the QS regulation requirements are basic, they will apply in total to most manufacturers and hospital SUD reprocessors.

The documentation necessary to meet the requirements of the QS regulation may vary with the complexity of the design and manufacturing operations, the size of the firm or facility, the importance of a process, and the risks associated with failure of the device. Small manufacturers, including hospital SUD reprocessors, may design acceptable quality systems requiring a minimum of documentation and, where possible, may automate documentation. In many situations, documentation can be kept at a minimum by combining many of the record-keeping requirements of the regulation, for example, the Standard Operating Procedures (SOPs), handling, and storage procedures.

FDA has prepared several guidance documents for the Quality System regulation and on subject matters that are significant to the QS regulation:

- *Medical Device Quality Systems Manual: A Small Entity Compliance Guide* includes discussion of the entire regulation plus examples of procedures and forms that can be adopted and modified by manufacturers and hospital SUD reprocessors; and,
- *Design Control Guidance For Medical Device Manufacturers* is intended to assist manufacturers and hospital SUD reprocessors in understanding the intent of the design control requirements. Assistance is provided by interpreting the language of the regulation and explaining in practical terms the underlying concepts.

These and other guidance documents can be found on the Internet at http://www.fda.gov/cdrh/dsma/cgmphome.html.

Design controls **do apply** to the reprocessing of SUDs. For example, hospital SUD reprocessors will be designing processes to clean, repair, and resterilize. All of these processes must be under design controls to ensure that the original device's specifications are not changed with regard to safety and effectiveness. This will entail design planning, design input, design output, design review, design verification, design validation, design changes, and the maintenance of a design history file. *Design Control Guidance for Medical Device Manufacturers*, while aimed at design controls for the original medical device, is equally as applicable to the design of processes for reprocessing SUDs. Further, the guidance is an excellent tool by which to become familiar with the regulatory language and expectations for the QS regulation requirements.

The Global Harmonization Task Force has produced a valuable guidance document entitled *Process Validation for the Medical Device Industry* that is available on the Internet at http://www.ghtf.org/sg3/inventorysg3/sg3-n99-10.doc.

FDA has prepared a 4-hour series of videotapes discussing the QS regulation. The videotapes are to be used with the guidebook entitled *The FDA and World Wide Quality System Requirements Guidebook for Medical Devices*. The guidebook contains the QS regulation, the text of ISO 9001:1994, FDA guidance from the preamble of the QS regulation, and guidance on quality systems from the Global Harmonization Task Force. The videotapes and guidebook are available from several different trade organizations including the American Society for Quality (ASQ) Biomedical Division, the Association for the Advancement of Medical Instrumentation (AAMI), the Food and Drug Law Institute (FDLI), and the Regulatory Affairs Professional Society (RAPS). The guidebook may also be purchased directly from ASQ Quality Press by calling 1-800-248-1946 and requesting number H0965.

FDA also provides guidance, conducts workshops to help with compliance activities, and participates in conferences, workshops, and meetings. See FDA's website at http://www.fda.gov/cdrh/dsma/cgmphome.html for a list of meetings and conferences. ✿

Kimberly Trautman, M.S. Biomedical Engineer, is FDA's Medical Device Quality Systems Expert and works in CDRH's Office of Compliance.

For information about classification, see the Registration and Listing article (page 4) and Appendix A of the Enforcement Priorities guidance at http://www.fda.gov/cdrh/ode/guidance/1331.pdf.

LABELING AND TRACKING REQUIREMENTS

As manufacturers, hospital reprocessors of single-use devices (SUDs) also must comply with the regulatory requirements of device labeling and device tracking.

Labeling

Reprocessed SUDs must be labeled according to the requirements of the Federal Food, Drug, and Cosmetic Act as amended and Title 21 of the *Code of Federal Regulations (CFR)* Part 801. Premarket Approval (PMA) applications and Premarket Notification (510(k)) submissions must include proposed labeling for the reprocessed SUD (21 CFR 807.87(e) and 814.20(b)(10)).

The Food and Drug Administration (FDA) has general labeling requirements regarding the name and place of manufacture and the inclusion of adequate directions for use. The guidance document entitled *Labeling Regulatory Requirements for Medical Devices* is available on FDA's Internet site at http://www.fda.gov/cdrh/dsma/470.pdf, by contacting the Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 or by calling Facts-On-Demand at 1-800-899-0381 or 301-827-0111 (specify number 470 when prompted for the document number). FDA plans to release additional information about the labeling of SUDs on its Reuse website at http://www.fda.gov/cdrh/reuse/index.shtml.

Tracking

The purpose of medical device tracking is to ensure that manufacturers of certain devices establish tracking systems to promptly locate devices in commercial distribution in the event a corrective action or notification about a device is necessary. Manufacturers and reprocessors of SUDs are not subject to medical device tracking, unless FDA issues a direct order to the manufacturer or hospital SUD reprocessor for a specific type of device. Additional information about device tracking, including the types of devices currently subject to tracking orders, is available in the FDA document entitled *Guidance on Medical Device Tracking*. This guidance document is available from DSMA's Facts-On-Demand (see above; specify number 169) or from the FDA Internet site at http://www.fda.gov/cdrh/modact/tracking.pdf. ✿

MEDICAL DEVICE REPORTING

by Beverly Albrecht Gallauresi, R.N., B.S., M.P.H.

Adverse event reports submitted under the Medical Device Reporting (MDR) regulation, (Title 21 of the *Code of Federal Regulations* (CFR) Part 803) provide the Food and Drug Administration (FDA) with information about the postmarket experience of medical devices. Manufacturers, importers, and user facilities (hospitals, nursing homes, outpatient diagnostic and treatment facilities, and ambulatory surgical centers) are subject to the MDR requirements and must establish and maintain files for adverse-event reports.

Information in these reports helps FDA to identify actual or potential device-related problems posing a risk to public health. In addition, FDA uses the MDR information to determine if product labeling needs improvement, if a device needs to be recalled, if user education programs are needed, and if FDA needs to conduct postmarket studies to obtain additional data on the safety and/or effectiveness of a particular device. For additional information about the MDR requirements, visit the Medical Device Reporting website at: http://www.fda.gov/cdrh/mdr.html.

On August 14, 2000, FDA announced in a guidance document entitled *Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals* that hospital reprocessors of single-use devices (SUDs) will be required to meet the same manufacturer requirements as the Original Equipment Manufacturer (OEM). A copy of the August 14, 2000 guidance document can be found on the Internet at: http://www.fda.gov/cdrh/reuse/1168.html.

Hospitals that engage in manufacturing activities, such as reprocessing SUDs, will be subject to the manufacturer reporting requirements for the reprocessed SUD as well as the user facility reporting requirements (21 CFR Part 803 Subpart A, C and E). A guidance document entitled *Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use*, dated April 24, 2001, is posted on the Internet at: http://www.fda.gov/cdrh/osb/guidance/1334.html.

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Below are the types of events that a hospital SUD reprocessor must begin reporting when an adverse event is related to a SUD that it has reprocessed:

Deaths

- As a hospital SUD reprocessor, report adverse events to FDA within **30** calendar days when information reasonably suggests that a SUD reprocessed by the hospital has or may have caused or contributed to the death of a patient at the facility. (21 CFR 803.50(a)(1))
- As a user facility, report to FDA and the device manufacturer within **10** working days when information reasonably suggests that the reprocessed SUD has or may have caused or contributed to the death of a patient at the facility. (21 CFR Part 803.30(a)(1))

Serious Injuries

- As a SUD hospital reprocessor, report adverse events to FDA within **30** calendar days when information reasonably suggests that a SUD reprocessed by the hospital has or may have caused or contributed to a serious injury to a patient at the facility (21 CFR 803.50(a)(1)).
- As a user facility, report to the device manufacturer within **10** working days when information reasonably suggests that a SUD reprocessed by the hospital has or may have caused or contributed to a serious injury to a patient at the facility. (21 CFR 803.30(a)(2))

Malfunctions that do not result in death or serious injury

- As a hospital SUD reprocessor, report adverse events to FDA within **30** calendar days when information reasonably suggests that a SUD reprocessed by the hospital has malfunctioned and such device or similar SUD, also reprocessed by the hospital, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. (21 CFR 803.50(a)(2))
- As a user facility, hospitals are not obligated to report malfunctions. However, FDA encourages voluntarily reporting of malfunction events through the MedWatch program. For additional information on FDA's MedWatch program, visit the MedWatch website at: http://www.fda.gov/MedWatch.

5-Day Reports

As a hospital SUD reprocessor, report adverse events to FDA within **5** working days after becoming aware of:

- event(s) that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, or
- reportable event(s) for which FDA has made a written request. (21 CFR 803.53)

Baseline Reports

As a hospital SUD reprocessor, submit an Initial Baseline report on FDA form 3417 or its electronic equivalent as approved by the agency under 21 CFR 803.14, for each reprocessed SUD device model that you are reporting to FDA for the first time. (21 CFR Part 803.58)

Written MDR Procedures and Files

Hospitals that reprocess SUDs are responsible for developing written MDR procedures and medical device complaint files. The hospital SUD reprocessor must conduct an investigation, including failure analysis and an evaluation of the cause of an adverse event involving its reprocessed SUD. If a hospital cannot provide complete information on a reportable event, it must provide statements explaining why such information was incomplete and the steps taken to obtain the information. (21 CFR Parts 803.17 and 803.18)

Supplemental Reports

Any required information obtained after filing the initial report must be provided to FDA in a supplemental or follow-up report. (21 CFR Part 803.56) ✿

Beverly Albrecht Gallauresi, R.N., B.S., M.P.H., is a Nurse Consultant in CDRH's Office of Surveillance and Biometrics.

UPCOMING REUSE EVENTS

August 15-18, 2001, American Society for Healthcare Central Service Professionals, Washington, D.C., FDA Speaker: Lily Ng. For information call Sharon Warren at (312) 422-3856 or visit their website: http://www.ashcsp.org.

September 11, 2001, Central New York Healthcare Central Service Professionals, Verona, New York, FDA Speaker: Sharon Kalokerinos. For more information call Peg Galluppi at 315-338-7323

October 4-5, 2001, Texas Society of Infection Control Practitioners, Harlingen, Texas, FDA Speaker: Lily Ng. For more information: LaurieD.Jonsson@vbmc.org.

November 4-7, 2001, RAPS 2001 Conference, Baltimore, Maryland, FDA Speaker: Lily Ng. For more information: http://www.raps.org/educ/uprogs.cfm

November 9-10, 2001, Japanese Association for Operative Medicine, Tokyo, Japan, FDA Speaker: Tim Ulatowski.

For more information visit the Reuse website at:

http://www.fda.gov/cdrh/reuse/index.shtml

REPORTS OF CORRECTIONS AND REMOVALS

by Blix Winston, M.P.A., M.S.

Background

Hospitals and third-parties that reprocess devices labeled for single use are subject to Part 806 (Reports of Corrections and Removals) of Title 21 of the *Code of Federal Regulations* (CFR) (http://www.fda.gov/cdrh/devadvice/part806.html#contents). Hospitals must comply with Part 806 by **August 14, 2001**, while third-party reprocessors were required to comply on August 14, 2000.

Medical device manufacturers, including hospitals that reprocess single-use devices (SUDs), make changes (corrections) to devices or remove them from use (removals) for a variety of reasons. Some of these steps are taken simply to service the device or to improve performance or quality. Sometimes, however, a device is modified or withdrawn, because the hospital has discovered a problem that, if left uncorrected, could place patients at risk. **Part 806 applies to any correction or removal; requires a hospital to keep records when any correction or removal occurs; and, in some cases, report their occurrences to the Food and Drug Administration (FDA)**.

Definition of Corrections and Removals

Section 806, like other requirements in the CFR, begins with a brief discussion of the scope of the regulation and then defines certain key words or concepts. A "correction" is:

> …the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

A "removal" is defined as:

> …the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Exemptions

FDA makes a distinction between improvements to performance or quality and corrections or removals taken to reduce a risk to health. Section 806.1(b) notes that the following corrections or removals are exempt (that is, they do not have to be reported to FDA):

- Actions taken by a hospital to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the Act caused by the device.
- Market withdrawals as defined in section 806.2(h).
- Routine servicing as defined in section 806.2(k).
- Stock recoveries as defined in section 806.2(l)

The definitions of market withdrawal, routine servicing, and stock recoveries can be found in section 806.2.

Risk to Health

"Risk to health" is defined in section 806.10(j) as:

- A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or
- That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or an outcome where the probability of serious adverse health consequences is remote.

Records and Reporting

Section 806.20 requires a hospital to keep records of any correction or removal, whether reportable or not. It also describes the information that must be retained by the hospital, including such things as the identity of the product, what action was taken, and a justification for not reporting the correction or removal to FDA. These records, while not reported, must be maintained for a period of 2 years beyond the expected life of the device and must be available to FDA upon request.

Corrections or removals that must be reported in writing to FDA within **10** working days are those undertaken to:

- reduce a risk to health posed by the device, or
- remedy a violation of the Act caused by the device which may present a risk to health….

What is a “violation of the Act?” The Federal Food, Drug, and Cosmetic Act (the Act) prohibits such things as "adulteration" or the "misbranding" of a device. A device that was improperly sterilized could be adulterated. A labeling mix-up occurring during reprocessing would result in a type of misbranding. Distributing either an improperly sterilized device or one with the wrong labeling would be considered a violation of the Act.

Information Needed when Reporting

Section 806.10 lists the information that must be reported to FDA. In addition to identifying information such as (device name, model numbers, and 510(k) or PMA numbers), Section 806.10 requires inclusion of the number of devices affected by the action and whether

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any injuries have occurred. Contact information for the consignees and a description of the event causing the correction or removal are to be included as well. If the hospital receives additional information about the product after sending a report to FDA, the original report must be amended within **10** working days. Reports of corrections or removals should be reported, in writing, to the local FDA district office. A list of these offices is available at http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.

It is important to note that by giving this information to FDA, the report does not constitute an admission that the device caused or contributed to a death or serious injury. It is often necessary for the hospital to investigate the incident to determine what actually happened and if the device caused or contributed to the adverse event. Once it has been submitted, a report can be made public (released) by FDA in response to a Freedom of Information request.

Summary

To summarize, a hospital is required to keep records of device corrections or removals, actions taken to reduce a risk to health, or actions to remedy a violation of the Act. A report of any action must be submitted to the local FDA district office within **10** working days of starting such an action.

Once a hospital determines that it must take a reportable action, it is a good idea to keep the FDA informed of what is happening after the report is submitted. For example, a hospital may move quickly to remove any unused products from its inventory. It is possible that by the time a report is sent to FDA, no unused product will still be available. On the other hand, it is not unusual to have large numbers of a batch of product in stock. Depending on the urgency of the required action, the hospital will want to work closely with the FDA to make sure a potential risk is eliminated quickly.

For more information about corrections and removals, visit the Device Advice website at http://www.fda.gov/cdrh/devadvice/51.html. Read and become familiar with 21 CFR Part 806. If you have questions, contact the Division of Small Manufacturers Assistance via email at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfDSMA/dsma-form.cfm. ✿

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USER FACILITY REPORTING BULLETIN

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

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