(CFR) classification (i.e., class I, class II, and class III). Upon issuance of this guidance document, the agency intends to enforce premarket submission requirements within six (6) months for all class III devices; within twelve (12) months for all class II non-exempt devices; and within 18 months for all class I non-exempt devices. At a later date, the agency will evaluate, on a case-by-case basis, the need to revoke exemptions from premarket submission requirements for class I and class II exempt products. Revocation of exemptions will be based on the agency's determination that premarket submissions for reprocessed devices in those classifications are necessary to ensure that these devices are safe and effective for reuse after reprocessing. The issuance of this guidance document does not preclude FDA from taking immediate action against any particular product that is causing significant harm.

B. Purpose

The purpose of this SUD Enforcement guidance document is to describe FDA's enforcement priorities to third parties and hospitals that reprocess SUDs. The enforcement priorities for premarket submission requirements are based on the device's CFR classification. Appendix A contains a list of SUDs known by FDA to be currently reprocessed for reuse in humans. This list is not comprehensive; it represents the agency's current knowledge of the types of SUDs that are being reprocessed. This list also contains information such as device classification, CFR regulation number and product codes (i.e., procodes) that the reader may find useful.

C. Scope

This guidance document is applicable to third party and hospital SUD reprocessors. The enforcement priorities set forth in this guidance do not apply to:

1. Permanently implantable pacemakers. The reuse of permanent pacemakers is addressed in Compliance Policy Guide 7124.12 (issued on October 1, 1980 and revised in March 1995);
2. "Opened-but-unused" SUDs (see Definitions in Appendix B);
3. Health care facilities that are not hospitals; or
4. Hemodialyzers. The reuse of hemodialyzers is addressed in "Guidance for Hemodialyzer Reuse Labeling (final draft issued on Oct. 6, 1995). A copy of this guidance is available on FDA's web site at www.fda.gov/cdrh/ode/dilreuse.pdf

FDA is aware that hospitals are not the only health care facilities that reprocess devices labeled for single use. At this time, the agency is limiting its focus to SUDs reprocessed by third party and hospital reprocessors. In the future and following experience with implementation of this guidance document, FDA intends to examine whether other establishments that reprocess SUDs should be included.

D. Why is FDA phasing in the enforcement of regulatory requirements for SUD reprocessors?

FDA believes that a phased-in approach for enforcement of regulatory requirements for third party and hospital reprocessors is appropriate for several reasons, including:

1. The agency believes that the health risk associated with reprocessing SUDs varies with each device and the agency's regulatory activities should be implemented in accordance with the device's CFR classification.
2. A phased-in implementation period may avoid any unintended and unpredictable consequences, such as potential shortages in certain hospitals, of an agency decision to immediately enforce all the requirements.
3. Establishments, such as hospitals, may be unfamiliar with FDA regulations, and a phased-in implementation approach will allow those facilities time to learn about the requirements and to develop programs to comply with them.
4. The agency's limited resources do not permit immediate enforcement of all regulatory requirements on third party and hospital reprocessors.

However, FDA emphasizes that nothing in this guidance document, including the phased-in enforcement approach that the agency intends to implement, precludes the agency from taking immediate action against any particular product that is causing harm.

E. What are the Act's requirements that apply to third party and hospital reprocessors?

The requirements that apply to third party and hospital reprocessors are:

1. Registration and Listing (Section 510 of the Act; 21 CFR Part 807);
2. Medical Device Reporting (Sections 519(a)(b) and (c) of the Act; 21 CFR Part 803);
3. Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821);
4. Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806);
5. Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820);
6. Labeling (Section 502 of the Act; 21 CFR Part 801); and
7. Premarket Requirements (Sections 513 and 515 of the Act; 21 CFR Parts 807 and 814).

Each of these regulatory requirements is described briefly below, with a citation to the corresponding section of the Act, FDA regulation in the CFR, and to other FDA guidances that may help in understanding a particular requirement (see Appendix C for additional guidances that may be helpful). FDA may issue additional guidances as needed.

1. Registration and Listing (Section 510 of the Act; 21 CFR Part 807):

Owners and operators of establishments who process devices must register their establishment with FDA, and provide a list of their devices. Establishments that are registering for the first time must use Form FDA-2891 ("Initial Registration of Device Establishment").

All SUDs that an establishment reprocesses must be reported on Form FDA-2892 ("Medical Device Listing"). A separate Form FDA-2892 must be submitted for each category or type of device that a reprocessor reprocesses.

Forms FDA-2891 and FDA-2892 can be obtained by mail from the Office of Compliance, Center for Devices and Radiological Health (HFZ-307), Food and Drug Administration, 2094 Gaither Road, Rockville, MD 20850.

Additional details regarding registration and listing are available in "CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA-2891, 2891a, and 2892". This guidance may be obtained by contacting the Division of Small Manufacturers Assistance (DSMA) by calling Facts on Demand at 1-800-899-0381 or 301-827-0111 (please specify number 012 when prompted for the document number) or from FDA's web page at www.fda.gov/cdrh/dsma/rlman.html

2. Medical Device Reporting (Sections 519 (a)(b) and (c) of the Act; 21 CFR Part 803):

Manufacturer's reporting requirements and other requirements under this regulation are more extensive than device user facility requirements. Hospitals who engage in manufacturing activities, such as reprocessing, are subject to manufacturer reporting requirements for the SUDs that they reprocess as well as user facility reporting requirements (21 CFR 803 Subpart E). In addition, they also must adhere to user facility reporting requirements for all other medical devices that they use (21 CFR 803 Subparts A and C). FDA realizes that hospitals that reprocess SUDs may need additional guidance from the agency on how to submit manufacturer adverse event reports. Accordingly, FDA plans to provide additional guidance to hospital reprocessors about applicable manufacturing adverse event requirements.

Further assistance in understanding medical device reporting (MDR) is available in a series of FDA publications. The most recent changes to the MDR requirements were published as a Final Rule in January 2000 entitled "Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting" in the Federal Register[7]. A copy of the December 1995 and January 2000 MDR Final Rules and other related MDR documents and guidances are available on FDA's web page at www.fda.gov/cdrh/mdr.html

[7] 65 FR 4112-4121 Jan. 6, 2000.

3. Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821):

The purpose of medical device tracking is to ensure that manufacturers of certain devices establish tracking systems that will enable them to promptly locate devices in commercial distribution in the event corrective actions or notifications about the device are necessary. Manufacturers are not subject to the Medical Device Tracking regulation unless and until FDA issues a direct order to the manufacturer. Accordingly, reprocessors will not be subject to the Tracking regulation unless FDA issues an order for the specific device(s) being reprocessed. Additional information on device tracking, including the types of devices subject to tracking orders, is available in FDA's "Guidance on Medical Device Tracking." Guidance can be obtained from CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 (please specify number 169 when prompted for the document number) or on FDA's web page at www.fda.gov/cdrh/modact/tracking.pdf

4. Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806):

All device manufacturers must report to FDA, within a specified time, certain types of device corrections and removals. In addition, each manufacturer must maintain records of all corrections and removals. Each device manufacturer also must submit a written report to FDA of any correction or removal of a device initiated by the manufacturer if the correction or removal was undertaken to reduce a risk to health posed by the device,

or to remedy certain violations of the Act. The term "correction" is defined in 21 CFR 806.2(e) as "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." The term "removal" is defined in 21 CFR 806.2(i) as the "removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection."

The following is an example of when the corrections and removal regulation is applicable:

> A hospital had reprocessed some SUDs that resulted in a patient experiencing an adverse health event. If the hospital pulls the remaining devices from the suspect batch or lot off their shelves to reduce the risk to health, this action would be considered to be a removal that must be reported to FDA.

5. Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820):

Current good manufacturing practice (cGMP) requirements are set forth in the Quality System regulation that governs the methods used in, and the facilities and controls used for the design, manufacturer, packaging, labeling, storage, installation, and servicing of all finished devices. These requirements include design controls (see 21 CFR 820.30), corrective and preventive action requirements (see 21 CFR 820.100), and process validation requirements (see 21 CFR 820.75). Guidance and information on the various

aspects of the Quality System regulation are available in the following documents: "Guideline on General Principles of Process Validation" (available at www.fda.gov/cdrh/ode/425.pdf or contact DSMA at the telephone numbers previously listed); "Design Control Guidance" (available at www.fda.gov/cdrh/comp/designgd.html); "Quality System Inspection Technique (QSIT) (available at www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF); and "Medical Device Quality Systems Manual: A Small Entity Compliance Guidance (available at www.fda.gov/cdrh/dsma/gmp_man.html).

Design control requirements are not applicable to all devices. Design control requirements apply to all class II, class III, and some class I devices (see 21 CFR 820.30).

6. Labeling (Section 502 of the Act; 21 CFR Part 801):

FDA has general labeling requirements regarding the name and place of manufacture and the inclusion of adequate directions for use. FDA's guidance "Labeling Regulatory Requirements for Medical Devices" contains relevant information. Guidance is available at the FDA web site www.fda.gov/cdrh/dsma/470.pdf or contact DSMA at the telephone numbers previously listed.

7. Premarket Requirements (Sections 510, 513 and 515 of the Act; 21 CFR Parts 807, and 814):

a. What type of premarket submission should I submit?

There are two types of premarket submissions - a premarket notification (or 510(k)) and a premarket approval application (PMA).

In general, the type of submission you submit depends on the CFR classification of the device. The classification regulation for a medical device, as provided under 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 (510(k)) submission is required for class I and class II devices. Class III devices may require either a premarket notification (510(k)) submission or a premarket approval (PMA) application, depending on the particular type of class III device. The classification regulation for each type of class III device indicates whether a premarket approval application is required.

For your convenience, FDA has indicated on the list of known reprocessed SUDs (see Appendix A), the type of marketing application that is required for each type of device.

b. What information do I need to include in my 510(k) submission in order to obtain FDA's marketing clearance for my device?

Your 510(k) submission must contain enough information for FDA to determine whether your device is as safe and effective as a legally marketed predicate device (i.e., "substantially equivalent" within the meaning of section 513(i) of the Act). As the 510(k) applicant, it is your responsibility to identify a legally marketed predicate device for the SUD you wish to reprocess. Keep in mind that the predicate device you select must have the same intended use as the device in your 510(k) submission. For a reprocessed SUD, the legally marketed predicate device for comparison may be the SUD of the OEM. The information in your 510(k) submission must compare the unique characteristics of your device to the predicate device so that it establishes that they are equivalent with respect to safety and effectiveness factors.

The criteria that FDA uses in deciding to grant marketing clearance for 510(k) submissions are more fully described in section 513(i) of the Act and 21 CFR 807.100. Your 510(k) application must include all the information described in the 510(k) regulation, 21 CFR 807.87. General guidance on the information that needs to be submitted in 510(k) submissions is available in FDA guidance "Premarket Notification 510(k): Regulatory Requirements for Medical Devices." A copy of this guidance can be found at www.fda.gov/cdrh/manual/510kprt1.html or contact DSMA at the telephone numbers previously listed. In preparing your submission, you should search CDRH's web site, assemble all relevant guidances for your specific device or specific

processes, complete the tests and compile the information as recommended. The web site address to search for applicable FDA guidances is www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGP/Search.CFM. For additional assistance, contact DSMA at the telephone numbers previously listed.

c. *What information do I need to include in my PMA in order to obtain FDA's marketing approval for my device?*

FDA's basis for approval of a PMA is a finding that the device has a reasonable assurance of safety and effectiveness for its intended use based on valid scientific evidence. Your PMA application must include valid scientific evidence that demonstrates the safety and effectiveness of your reprocessed SUD. Submission of clinical data may be necessary in order to establish a device's safety and effectiveness. Your PMA application also should evaluate the unique characteristics of your device. The factors that FDA uses to grant marketing approval of PMAs are more fully described in section 515(d) of the Act and 21 CFR 814.44.

A description of what the agency considers a complete PMA application is available in the PMA regulation, 21 CFR 814.20. FDA has general guidances on the information that needs to be submitted in PMA applications (see FDA's "Guidance for Preparation of PMA Manufacturing Information." A copy can be obtained from www.fda.gov/cdrh/ode/448.pdf).

To assist you in submitting your PMA application for specific products, FDA has posted device-specific and process-specific guidances on its worldwide web site to supplement the general requirements noted above. You can search for applicable FDA guidances at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGP/Search.CFM or contact DSMA at the telephone numbers previously listed.

In addition to reviewing the data in a PMA application, FDA also requires a satisfactory inspection of your manufacturing facilities before a PMA application can be approved. Therefore, your PMA application must include a comprehensive manufacturing section, which clearly identifies all appropriate manufacturing controls. Guidance about manufacturing information to include in premarket submissions is available in "Guidance on Quality System Regulation Information for Various Pre-market Submissions." A copy of this guidance can be obtained at www.fda.gov/cdrh/dsma/cgmphome.html or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 (please specify number 1140 when prompted for the document number). Reprocessors and hospitals that intend to reprocess devices that will require a PMA should be prepared for a pre-approval inspection.

d. What happens if a third party or hospital reprocessor fails to submit a 510(k) submission or a PMA application or makes a submission that is administratively incomplete?

A third party or hospital that decides to stop reprocessing SUDs will not be required to make any submission to the agency. Third parties and hospitals that continue reprocessing SUDs must make the appropriate and timely submission described below.

FDA initially will review your 510(k) submission or PMA application to make a threshold determination as to whether it contains sufficient information to begin a substantive review. If the submission or application does not, on its face, contain all the information required under 21 CFR 807.87(for 510(k)s) or 21 CFR 814.20 (for PMAs), FDA will not review that application or submission any further and the file will be placed on hold (see 21 CFR 807. 87 and 814.42(e)). You may submit the additional information to complete the file. However, the agency does not consider such submissions to satisfy the premarket submission requirements or the intent of the phase in enforcement period. FDA intends to take immediate enforcement action against third party and hospital reprocessors that fail to make any submissions or submit administratively incomplete 510(k)s or PMA applications following the end of the phase in periods identified in this document.

In addition, the agency wants submitters to realize that a 510(k) submission or PMA application that is administratively complete may nevertheless be difficult to review if it is poorly organized or does not address device specific issues. In these situations, there are likely to be delays in premarket review.

e. *What happens if a third party or hospital reprocessor submits a 510(k) submission or a PMA application that is scientifically inadequate?*

FDA may take enforcement action against third party and hospital reprocessors who submit scientifically inadequate 510(k) submissions or PMA applications or whose 510(k) application or PMA submission is still under review after the end of the phase in periods identified in this document (see "F. Enforcement priorities and periods of enforcement discretion for FDA requirements" below).

f. *Can I combine several different models and brands of the same type of device into one 510(k) submission or PMA application?*

Premarket (510(k)) submissions and PMA applications are device specific; FDA requires a 510(k) or a PMA for each device. Only closely related variations of the same type of device should be grouped in one submission or application. FDA advises reprocessors to examine device groupings that OEMs have developed in previous submissions as models that may be useful in considering the groupings of reprocessed SUDs. Data and information in the submission or application must support the substantial equivalence (510(k)) or safety and effectiveness (PMA) of the entire group of devices in a marketing submission.

g. *What if I need to conduct clinical studies as part of my 510(k) submission or PMA application?*

FDA regulations (21 CFR Parts 50, 56, and 812) describe the procedures for the conduct of clinical studies used to support marketing submissions. Class III and class II may be considered significant risk devices, as defined in 21 CFR 812.3(m). Clinical studies of significant risk devices need prior FDA approval of an investigational device exemption (IDE) application before the study may begin. Clinical studies need prior approval of the local institutional review board and informed consent from the patient. Additional information on IDE requirements is available in two FDA guidance documents: "Significant and Non-significant Risk Medical Device Studies" (accessible at www.fda.gov/cdrh/manual/idemanul.html) and "IDE Policies and Procedures" (accessible at www.fda.gov/cdrh/ode/idepolcy.html). Copies of these guidances can also be obtained by contacting DSMA at the telephone numbers previously listed.

F. Enforcement Priorities and Periods of Enforcement Discretion for FDA Requirements

Upon issuance of this guidance document, FDA intends to enforce the regulatory requirements listed under section E of this guidance using a combination of a phased-in approach and continued enforcement discretion. A brief description of these requirements and their time lines are provided below.

FDA intends to actively enforce the Act's premarket submission requirements for third party and hospital reprocessors six (6) months following issuance of this guidance

document for devices classified as class III; within twelve (12) months for devices classified as class II; and within eighteen (18) months for devices classified as class I. FDA intends to take enforcement action against any third party or hospital reprocessor that fails to meet these deadlines (i.e., referring to the 6, 12, and 18 month deadlines for premarket submissions), or the deadlines described below.

FDA intends to actively enforce the Act's non-premarket requirements for hospital reprocessors one (1) year following issuance of this guidance document. FDA intends to use the first year following issuance of this guidance document to educate hospitals about their regulatory obligations under the Act.

FDA intends to continue to enforce all non-premarket requirements against third-party reprocessors.

The agency's use of a phased-in approach and enforcement discretion to enforce the Act's premarket submission and other requirements does not preclude FDA from taking enforcement action sooner than the time periods described if the agency determines that any reprocessed medical device presents a significant risk to public health. Conversely, the agency may continue to exercise its discretion to not actively enforce FDA requirements for longer periods of time than described below when there may be shortages of medically necessary devices, constraints on agency resources, or for other compelling reasons.

1. Enforcement Discretion Period for Premarket Requirements (Sections 513, and 515 of the Act; 21 CFR Parts 807 and 814):

The following describes the agency's enforcement discretion period for premarket submission requirements. However, we encourage all reprocessors to submit premarket submissions to FDA even before the premarket submission requirement implementation dates listed in this guidance document. We believe that this will be helpful to all parties because the agency will learn what types of submissions to expect while reprocessors can obtain feedback on their 510(k) submissions or PMA applications before the agency actively enforces its premarket submission requirements.

a. SUDs categorized as class III devices:

FDA intends to continue to exercise its enforcement discretion with respect to premarket submission requirements for third party and hospital reprocessors of class III devices for one (1) year from the date of issuance of this enforcement guidance provided that:

1. FDA receives a 510(k) submission or a PMA application no later than six (6) months following the issuance of this enforcement guidance;
2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7. *d* and *e*); and

3. The applicant receives an FDA order finding the device substantially equivalent to a legally marketed predicate and cleared for marketing, or an order approving a premarket approval application, within twelve (12) months of issuance of this guidance document.

Upon issuance of this guidance document, FDA intends to take enforcement action against any third party or hospital reprocessor who fails to satisfy all of the conditions described above.

b. SUDs categorized as class II non-exempt devices:

FDA intends to continue to exercise its enforcement discretion with respect to premarket submission requirements for third party and hospital reprocessors of class II non-exempt devices for eighteen (18) months from the date of issuance of this enforcement guidance provided that:

1. FDA receives a 510(k) submission no later than twelve (12) months following issuance of this enforcement guidance;
2. The 510(k) submission is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7. *d* and *e*); and
3. The applicant receives an FDA order finding the device substantially equivalent to a legally marketed predicate and cleared for marketing within eighteen (18) months of issuance of this guidance document.

Upon issuance of this guidance document, FDA intends to take enforcement action against any third party or hospital reprocessor who fails to satisfy all of the conditions described above.

c. *SUDs categorized as class I non-exempt devices:*

For third party and hospital reprocessors of class I non-exempt devices, FDA intends to continue to exercise its enforcement discretion with respect to premarket submission requirements for these devices for two (2) years from the date of issuance of this enforcement guidance provided that:

1. FDA receives a 510(k) submission no later than eighteen (18) months following issuance of this enforcement guidance;
2. The 510(k) submission is complete and is of sufficient quality to be acceptable for substantive review (see discussion under 7.*d* and *e*); and
3. The applicant receives an FDA order finding the device substantially equivalent to a legally marketed predicate and cleared for marketing within twenty-four (24) months of issuance of this guidance document.

Upon issuance of this guidance document, FDA intends to take enforcement action against any third party or hospital reprocessor who fails to satisfy all of the conditions described above.

d. *SUDs categorized as class I exempt or class II exempt devices*: