

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Preface**

**Public Comment:**

The Food and Drug Administration (FDA) is announcing the availability of a document that describes the agency's proposed strategy on reuse of single-use devices. Written comments and suggestions regarding this document should be submitted to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5603 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Comments and suggestions should be identified with the docket number (XXX).

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## **Introduction**

This document describes the FDA's proposed strategy to address the reuse of medical devices currently labeled, or otherwise intended, for only one use. The agency is soliciting comments, proposals for alternative approaches, and information on this issue from stakeholders and interested parties.

## **Background**

The practice of reusing medical devices labeled, or otherwise intended, for only one use (referred to as "single-use devices") began in hospitals in the late 1970s. Prior to this time, most medical devices were considered to be "reusable" (i.e., equipment that is used and reprocessed multiple times). Because most of the reusable devices were fabricated from glass, rubber, or metal, early reprocessing of reusable products such as probes and surgical instruments involved little more than handwiping, dipping, and soaking in disinfection solutions of glutaraldehyde, hydrogen peroxide, or peracetic acid. Original Equipment Manufacturers (OEMs) began to sell "single-use" medical devices as a result of market demand for disposable equipment, the development of new plastics, and the use of ethylene oxide sterilization. Hospitals began to see products labeled "single-use only" that were similar to devices that had been formerly distributed or continued to be distributed as "reusable". It is believed that the practice of reprocessing single-use devices (SUDs) expanded when an increasing number of hospitals decided that reuse was a cost-saving measure and when the amount of medical waste generated by the use of disposable devices became noticeable. The decision to reuse SUDs led hospitals to start reprocessing more complex products (e.g., balloon angioplasty catheters and

cardiac catheters) that required more involved decontamination sterilization procedures, such as wiping the device of visible soil at the point of use, containing and transporting the device to a decontamination or sterilization work area, decontaminating, or performing a terminal microbicidal process like sterilization. As a result, an industry of third-party reprocessors evolved in response to the reprocessing needs of hospitals.

The expansion of an industry of third-party reprocessors and the types of single-use products subjected to reprocessing intensified concern regarding patient safety, informed consent, the ethics of this practice, and equitable regulation of OEMs and reprocessing firms.

An OEM may label a medical device for either multiple use (e.g., an x-ray machine, a ventilator, an infusion pump) or single use (e.g., an implantable device, an endotracheal tube, examination gloves). Remarketing industries exist for both of these types of devices. These remarketing activities may consist of reprocessing, refurbishing, rebuilding, servicing, reconditioning, cosmetically enhancing, or marketing a device “as is” for reuse. In some cases, such remarketing activities may have the potential to significantly change a finished device’s performance, safety specifications, or intended use. Entities who engage in these activities have been defined in the Quality System regulation as a “remanufacturer” of devices (21 CFR 820.3(w)). Reprocessing SUDs is one type of remanufacturing activity.

The proposed strategy described in this document only applies to remanufacturing activities related to the reuse of SUDs. It does not apply to other types of remarketing or remanufacturing activities.

## **The FDA's Current Policy Regarding Reprocessing SUDs**

Establishments that engage in manufacturing activities, including reprocessing of SUDs for reuse, may be subject to all requirements of the Federal Food, Drug, and Cosmetic Act (Act) including: registration and listing (21 CFR Part 807); premarket notification and approval requirements (21 CFR Parts 807 and 814); submission of adverse event reports under the Medical Device Reporting (MDR) regulation (21 CFR Part 803); manufacturing requirements under the Quality Systems (QS) regulation (21 CFR Part 820); Labeling requirements (21 CFR Part 801); Medical Device Tracking (21 CFR Part 821); and Medical Device Corrections and Removals (21 CFR Part 806).

The FDA has not regulated OEMs, third-party reprocessors, and health care facilities the same manner with respect to SUDs.

OEMs have been subject to all the requirements described above. The agency described the current regulatory responsibilities of hospitals that engage in reprocessing in Compliance Policy Guide (CPG) 300.500 (issued on November 11, 1977). This CPG states that hospitals that reprocess SUDs assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized, and that device safety, effectiveness, and quality are maintained. The FDA has not issued a CPG that addresses third-party reprocessors of SUDs, although the agency has issued statements in response to specific inquiries. Under current agency policy, third-party reprocessors are subject to registration, listing, QS, labeling, and MDR reporting requirements. A recent letter from the Director, Division of Enforcement III, Office of Compliance, stated that third-party reprocessors are subject to premarket requirements. The FDA notes, however, that many devices that are commonly

reprocessed are exempt, by regulation, from premarket requirements. Over the years, the agency has issued Warning Letters to third-party reprocessors for a variety of violations: failure to comply with quality systems requirements, including failure to validate sterilization procedures (21 CFR Part 820); failure to carry labeling statements that a device has been reprocessed (21 CFR Part 801.1); and failure to bear adequate directions for use (21 USC 352(f)(1)). While the regulations may require third-party reprocessors who engage in certain manufacturing activities to comply with premarket requirements, the FDA, in its enforcement discretion, has not taken action against third-party reprocessors on the basis of noncompliance with premarket notification requirements.

Until the agency completes its examination of the SUD policy and issues a final policy, the FDA does not intend to change its policy with respect to third-party reprocessors or health care facilities that reprocess. This does not preclude the FDA from taking any appropriate regulatory action should a reprocessed medical device present a significant risk to the public health.

#### **May 1999 FDA and AAMI Conference on Reuse**

On May 5-6, 1999, the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) cosponsored a conference at Crystal City, Virginia on the practice of reprocessing and reusing SUDs. Among conference attendees and participants were representatives of health care facilities, firms that reprocess devices, OEMs, national oversight organizations, state governments, academia, medical ethicists, and standards organizations. This provided the FDA the opportunity to hear a wide range

of views and concerns from individuals and organizations involved in or affected by this practice. Highlights of the issues discussed are summarized below.

**Regulation.** The FDA received divergent opinions on how reprocessing and reuse of SUDs should be regulated. Some participants believed that reprocessors should be regulated in the same manner as OEMs and that 510(k)s or Premarket Approval Applications (PMAs) demonstrating the safety and effectiveness of the reprocessed device should be required. Others felt that OEMs should be required to provide instructions on how to reprocess their devices unless they can demonstrate that the device cannot be reprocessed.

**Guidance and Standards.** Participants identified the need for additional guidance on reprocessing. Among the suggestions were: standards to assure that cleaning, disinfection, and sterilization processes are validated and that reprocessing may be performed properly; a determination of what types of devices can and cannot be reprocessed; a classification scheme establishing critical, semi-critical, and non-critical categories for reprocessed devices; and clearer definitions for the terms “reuse,” “reprocessing,” and “resterilization”.

**Obtaining data on reprocessing and reuse.** Participants suggested that clinical data and experience on reuse could be obtained through: hospitals’ existing surveillance activities; long-term clinical studies; the establishment of a clearinghouse for data; the dedication of National Institutes of Health funds to study reprocessing; and research to be conducted by professional societies with funding provided by OEMs and reprocessors.

Videotapes of the conference can be ordered from AAMI by calling 703-525-4890 ext. 260.

## **The FDA's Proposed Strategy on Reuse of SUDs**

The FDA is committed to reevaluating its position on the reuse of SUDs. To that end, the agency has developed and is making available for public review and comment this document, which describes the agency's proposed strategy to address reuse of SUDs. The FDA's primary goal is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science. This proposed strategy is, in part, the result of information and suggestions the agency received during the May 1999 FDA/AAMI conference.

The FDA is scheduling an open meeting, to be held in Rockville, Maryland on December 14, 1999 to obtain feedback from stakeholders and interested parties on its proposed strategy on reuse of SUDs. The agency will develop further policy, as appropriate, to implement its strategy on reuse based on comments it receives in response to this document and on information gathered at the open meeting.

The proposed strategy presents the various tasks that the FDA, OEMs, third-party reprocessors, health care facilities, professional health care associations and organizations, the standards development community, and other interested parties could perform to address concerns regarding the practice of reprocessing and reusing single-use products in the United States. The FDA plans to engage in an immediate effort to collect information from and work collaboratively with various stakeholders and interested parties in order to facilitate the development of a sound strategy. For ease of discussion, the agency's proposed strategy is divided into eight (8) sections:

1. Reconsider the agency's current policy on establishments that reprocess SUDs;

2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk;
3. Solicit comments on the FDA's draft list of "Frequently Reprocessed SUDs";
4. Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs;
5. Examine the need to create working definitions for the terms "single-use device", "reuse", "reprocessing", and "resterilization";
6. Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the safety, effectiveness, and performance of reprocessed SUDs;
7. Consider developing a research program on reuse of SUDs and explore avenues to publish and disseminate research and other information on reuse; and
8. Convene an open meeting on December 14, 1999 to discuss the agency's proposed strategy.

A discussion of each section of the proposed strategy follows.

**1. Reconsider the agency's current policy on establishments that reprocess SUDs.**

The FDA is reconsidering its current policy for establishments that reprocess SUDs. Based on concerns about the practice of reprocessing, the agency is considering a strategy to regulate third-party reprocessors and health care facilities that engage in reprocessing in the same manner that the agency has regulated OEMs.

The FDA recognizes that a decision to regulate health care facilities that reprocess in the same manner as other reprocessors will have a significant impact on the agency's resources, particularly for conducting inspections of these facilities. Therefore, if the agency proceeded to regulate health care facilities in the same manner as OEMs, the FDA would consider collaborating with accredited third-party organizations or other federal agencies to inspect these facilities to ensure that reprocessing operations are being performed in accordance with the agency's requirements.

**2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk.**

The FDA intends to explore the development of a risk-based categorization system to assist the agency in developing an enforcement strategy for reused SUDs. Under this approach, the agency's application of its authority would depend on the level of risk associated with the reprocessing and reuse of a particular SUD.

The FDA is seeking input from stakeholders and interested parties on factors that should be considered when evaluating a reprocessed SUD's risk to patients and users, as well as how its enforcement policy should be applied to these devices. The agency believes that the categorization system would be a three-tiered system ("low-risk", "moderate-risk", or "high-risk"). Single-use products that are reprocessed because sterility was breached by means other than patient contact would also be included in this risk categorization scheme. The FDA plans to develop a prototype categorization scheme

and to circulate it to OEMs, third-party reprocessors, health care professionals, and other interested parties for comment.

Factors that the FDA is considering that could determine an SUD's risk category include: the complexity of procedures associated with reprocessing the device; the actual and potential risk for infection should the reprocessed device be reused; and the quality and extent of published data on reprocessing for the specific device.

“High-Risk” Reprocessed SUDs:

The agency would consider “high-risk” SUDs to be products that may pose significant public health risk to patients and users after reprocessing. The FDA believes that products in this category should be removed from the market within a short time frame if they have not complied with applicable premarket requirements. For this “high-risk” category, the FDA is considering enforcing all of the agency's regulatory requirements, including premarket requirements, within six (6) months after a final agency policy on reuse is issued. Considering the type and regulatory class of SUDs that may be included in this category, it is likely that the premarket data that will be reviewed by the FDA for “high-risk” products will be submitted through the premarket approval process.

“Low-Risk” Reprocessed SUDs:

The agency anticipates that the “low-risk” category would include SUDs that pose little or no potential public health risk to patients or users after reprocessing. The agency believes that some of the devices in this category will be Class I and Class II exempt, and some Class I and II non-exempt.

The FDA expects that establishment inspections for entities that reprocess “low-

risk” SUDs to assure compliance with Good Manufacturing Practices (GMP) would be a low priority for the agency. In addition, the FDA plans to exercise enforcement discretion not to enforce 510(k) submission requirements, if applicable, for non-exempt products in this category, provided that the reprocessors have validated reuse procedures or declare conformity to a recognized consensus standard that is applicable to the reprocessed SUD (see section 6 for a detailed discussion of this option). The agency also plans to enforce all other requirements for products in the “low-risk” category, including registration and listing requirements. The agency anticipates that it would not enforce registration and listing requirements for these products for a six (6) month period after the FDA announces its final reuse policy.

“Moderate-Risk” Reprocessed SUDs:

The agency believes that “moderate-risk” SUDs would include those products that are not in the “low-” or “high-” risk categories. The FDA would enforce applicable premarket requirements for products in this category to ensure that the reprocessed device remains as safe and effective as a never-used SUD. This might be accomplished by allowing reprocessors to make declarations of conformity to recognized consensus standards to comply with premarket requirements (see section 6 for a detailed discussion of this option).

The agency would plan to utilize its enforcement discretion to not enforce premarket requirements for “moderate-risk” SUDs for a period of two (2) years provided reprocessors collect, retain, and maintain postmarket data to document the safety, effectiveness, and performance of reprocessed SUDs in this risk category. The agency is soliciting comments on the type of postmarket data reprocessors should collect during the

two-year enforcement discretion period.

The agency also would require reprocessors of devices in the “moderate-risk” category to comply with registration and listing, labeling, corrections and removals, quality systems, and tracking. As with “low-risk” products, the FDA would not plan to enforce registration and listing requirements for a period of six (6) months after the agency finalizes its reuse policy.

The FDA acknowledges that an SUD’s reuse category under this system should not be a permanent designation. The agency recognizes that the categorization system must provide flexibility in allowing SUDs to be moved from one category to another, as more data become available on the risks associated with reprocessing and reusing the device. In particular, the agency views the “moderate-risk” category as one that would contain many devices that are in transition. As data are collected on these products, some public health concerns may emerge and place certain products in the “high-risk” category, while other products may move into the “low-risk” category.

In order to support its premarket decisions on reused SUDs, the agency anticipates that the reprocessor would submit valid scientific evidence showing that SUDs can be reprocessed by the methods utilized by the reprocessor for a limited/specified number of times and still be safe and effective for their intended uses. Comments and input on this issue as it relates to reused SUDs are welcome.

### **3. Solicit comments on the FDA’s draft “List of Frequently Reprocessed SUDs”.**

The FDA is soliciting comments on its proposed list of “Frequently Reprocessed SUDs.” The devices, CFR regulation number, and classification are as follows:

- Surgical Saw Blades – 21 CFR 878.4820, Class I Exempt
- Saw Blades – 21 CFR 878.4800, Class I Exempt
- Surgical Cutting Accessories – 21 CFR 878.4800, Class I Exempt
- Surgical Drills – 21 CFR 878.4820, Class I Exempt
- Surgical Mesh – 21 CFR 878.3300, Class II
- Drill Bits – 21 CFR 878.4540, Class I Exempt
- Laparoscopy Scissors – 21 CFR 876.1500, Class I Exempt
- Endoscopic Carpal Tunnel Blades – 21 CFR 888.4540, Class I Exempt
- Orthodontic (metal) Braces – 21 CFR 872.4510, Class I Exempt
- Orthodontic (plastic) Braces – 21 CFR 872.5470, Class II
- Electrophysiology Catheters – 21 CFR 870.1220, Class II
- Electrosurgical Electrodes and Pencils – 21 CFR 878.4400, Class II
- Cardiac Catheters and Guidewires – Class II and III, 510(k) and PMA; unclassified
- Respiratory Therapy and Anesthesia Breathing Circuits – 21 CFR 868.5240, Class I Exempt
- Biopsy Needles – 21 CFR 878.4800, Class I Exempt; 21 CFR 876.1075, Class II
- Endotracheal Tubes – 21 CFR 868.5730, Class II
- Syringes – 21 CFR 880.5860, Class II
- Sutures – Class II and III, 510(k) and PMA, unclassified
- Staplers – 21 CFR 878.4800, Class I Exempt
- Balloon Angioplasty (PTCA) Catheters – Class II, PMA
- Biopsy Forceps – 21 CFR 876.1075, Class I Exempt, 21 CFR 874.4680, Class II
- Trocars – 21 CFR 874.4420, Class I Exempt, 21 CFR 870.1390, Class II

**4. Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs.**

The FDA is considering whether labeling information affecting reuse of SUDs should be provided by OEMs to health care providers and consumers. Existing statutes and regulations already require that devices bear adequate directions for use (Section 502(f)), and that the labeling not be false and misleading (Section 502(a)). One option the agency is considering is requesting OEMs who label their devices “single-use” to provide, as part of the device’s labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs. This information would serve as a caution to users and reprocessors who might attempt to reprocess these SUDs.

**5. Examine the need to create working definitions for the terms “single-use device”, “reuse”, “reprocessing”, and “resterilization”;**

As previously stated, during the May 1999 FDA/AAMI conference, several participants voiced the need to define commonly used terms associated with reuse. The definitions listed below are working definitions the agency is considering. The agency is interested in obtaining comments on the following:

A. Single-use device:

(1) Single-use disposable: a single-use device that is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned and disinfected/sterilized) and used on another patient. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single-use, disposable devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

(2) Opened but unused single-use device: a disposable single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.

B. Reuse: the repeated use or multiple uses of any medical device, including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.

C. Reprocessing: includes all operations performed to render a contaminated reusable or single-use device patient-ready or to allow an unused product that has been opened to be made patient-ready. The steps may include cleaning and disinfection/sterilization.

The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

D. Resterilization: the repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

**6. Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the safety, effectiveness, and performance of reprocessed SUDs.**

The FDA is interested in facilitating and, to whatever extent possible, participating in the evaluation of recognized consensus standards to determine their utility in reprocessing SUDs and identifying and developing device-specific standards for reprocessed SUDs. One possibility is to allow reproducers the option to declare conformity to a recognized standard to ensure that the device remains safe and effective for its intended use. The agency acknowledges that declarations of conformity to consensus standards are voluntary. Moreover, the FDA recognizes that there are a limited number of device-specific performance standards currently available for SUDs. Therefore, the agency will need to rely heavily on the cooperation and support of stakeholders and would expect interested parties to assume primary responsibility for the development of these standards.

**7. Consider developing a research program on reuse of SUDs and explore avenues to publish and disseminate research and other information on reuse.**

The FDA is interested in pursuing discussion on the need to develop a research program with a specific focus on reuse of SUDs. The agency has conducted several in vitro studies on reused SUDs and is considering, if resources permit, expanding these efforts for the purpose of increasing its scientific knowledge on how reprocessing affects SUDs. The FDA believes that the expansion of its research efforts may facilitate collaboration with stakeholders and interested parties to conduct more in vivo and in vitro studies. In addition, the FDA plans to publish the results of the scientific studies that it has conducted to date on reprocessed SUDs.

To ensure that the health care community, the manufacturer/reprocessor community, patients, and the public in general are fully aware of the current issues involving the reprocessing and reuse of SUDs, the FDA is considering an outreach program to disseminate information on its activities. Some avenues that the FDA is exploring include posting of talk papers, public health notifications, and lay articles for consumers on the FDA web page. The FDA also may sponsor satellite teleconferences on this subject. The first satellite teleconference on reuse is tentatively scheduled for November 10, 1999.

**8. Convene an open meeting on December 14, 1999 to discuss the FDA's proposed strategy.**

The FDA plans to convene an open meeting on December 14, 1999 to gather comments on its proposed strategy on reuse of SUDs. The meeting will be announced in a Federal Register notice in November 1999. At this meeting, the agency hopes to solicit offers of assistance from all stakeholders and interested parties to address the reuse issue expeditiously and effectively.