Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Three Additional Questions; Final Guidance for Industry and FDA Staff

Document issued July 9, 2002

This document contains three questions to be added to the 13 questions in *Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff*, July 6, 2001.

U.S. Departme nt of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
Division of Device User Programs and Systems Analysis

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance, contact Lily Ng at 301-796-5692

or by email to lily.ng@fda.hhs.

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/cdrh/ohip/guidance/1408.pdf you may also send and email request to dsmica@fda.hhs.gov to recieve an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use document number (1408) to identify the guidance you are requesting.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Background

On August 14, 2000, the Food and Drug Administration released a document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to provide guidance to third-party and hospital reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third-party and hospital reprocessors of single-use devices (SUD) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Section 513 and 515 of the Act; 21 *Code of Federal Regulations* Parts 807 and 814).

Since its release on August 14, 2000, the agency has received numerous questions about the enforcement priorities guidance. The following questions and answers are meant as clarification of the original document. This guidance will be updated as the need arises.

The Least Burdensome Approach

We believe FDA should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/

Question related to
APPENDICES

Question. What are the regulatory requirements for opened-but-unused SUDs reprocessed by a third-party (commercial) reprocessor?

Answer. The Food and Drug Administration's guidance document "Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals" (dated Aug. 14, 2000), defined *opened-but-unused* single-use devices (SUD) as "single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not been used on a patient, that is, they have not been in contact with blood or bodily fluids." (Appendix B, page 40)

In section "C. Scope" of the guidance document, it states that the enforcement priorities do not apply to *opened-but-unused* SUDs. This means that at this time, FDA is not requiring third-party or hospital reprocessors of SUDs to submit PMAs (premarket approval applications) or 510(k)s (premarket notification submissions) for open-but-unused SUDs. However, FDA's existing policy for *opened-but-unused* SUDs that are reprocessed by third parties remains unchanged: ***opened-but-unused* SUDs reprocessed by commercial reprocessors are subject to the Quality System Regulation (QSR)**.

Question related to
QUALITY SYSTEM

STERILIZATION

Question. Must a reprocessor of a single-use device (SUD) validate its cleaning/disinfection process if the device being reprocessed is not intended to be sterile?

Answer. Yes. Validation is needed because the results of the cleaning/disinfection process cannot be fully verified by subsequent inspection and testing. Furthermore, the fact that the device is nonsterile means there will not be a subsequent sterilization process to kill any contaminants remaining on the device after cleaning/disinfection.

Question related to
ENFORCEMENT DATES

Question. Since several extensions have been granted, what are the dates that hospital reprocessors of SUDs must meet?

Answer. The following tables summarize the regulatory requirements and the enforcement dates that apply to hospital reprocessors of SUDs.

DATES FOR MEETING
PREMARKET SUBMISSION REQUIREMENTS

PMA Applications (Premarket Approval) or 510(k) Submissions (Premarket Notification)	**Due by:**	**Cleared or approved by:**
Class III	February 14, 2001	February 14, 2002
Class II non-exempt	August 14, 2001	August 14, 2002*
Class I non-exempt	February 14, 2002	August 14, 2002

*Provided that the reprocessor

(1) submitted a premarket notification by August 14, 2001;
(2) has not received a "not substantially equivalent" determination; and
(3) provides timely responses to FDA's requests for additional information.

DATES FOR MEETING
NON-PREMARKET REQUIREMENTS

Registration and Listing	**August 14, 2001**
Medical Device Reporting (MDR)	August 14, 2002
Tracking	August 14, 2002
Corrections and Removals	August 14, 2002
Quality System Regulation	August 14, 2002
Labeling	August 14, 2002