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Part I: Background and Regulatory Framework

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Guidance for FDA Staff and Industry Sec. 300.500 Reprocessing of Single-Use Devices, March 18, 2005

This guidance document lists and explains regulations that reprocessors of single-use devices (SUDs) must comply with.

Section 2 11
Reprocessed Single-Use Device Timeline

The timeline lists requirements, action dates and actions needed by reprocessors of SUDs under the Medical Device User Fee and Modernization Act (MDUFMA) of 2002 (amended 2007).

Section 3 17
Reprocessing of Single-Use Devices; Frequently Asked Questions

This document provides answers to questions regarding topics such as: selection of third-party reprocessor, the Medical Device Reporting (MDR) system, the quality system (QS), sterilization, specific devices, and registration and device listing.

Section 4 25
Definitions

These definitions provide the meaning of key terms related to the reprocessing of SUDs.

Part II: MDUFMA, 510(k) and Validation

Section 5 31
Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended — Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices, May 2006

Section 301 of MDUFMA amended Section 502 of the Federal Food, Drug and Cosmetic Act (FDCA) to require a device to bear the name of the manufacturer. This guidance document includes definitions, explains how the provision applies to SUDs, how to know whether a manufacturer’s mark is prominent and conspicuous, and when a reprocessor should place its mark on a device. It also includes a flow chart to help reprocessors decide whether to place their mark on the device, use a detachable label or use an attachment.

Section 6 45***Guidance for Industry and FDA Staff Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices, September 2006 [amended 2007, see Section 14]***

This guidance document describes the types of validation the FDA recommends to be submitted under 510(k) of the FDCA. It also provides guidance on submission and review procedures for validation. The FDA also offers definitions, a question-and-answer section on the MDUFMA 510(k) requirements, an overview of validation data and information on the reprocessing procedure, such as cleaning, packaging and sterilization.

Section 7 65***Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data, Federal Register, Sept. 25, 2006***

The *Federal Register* announced that the FDA was amending classification regulations for reprocessed SUDs whose exemption from 510(k) had been terminated. It provides background, definitions, explains critical and semicritical devices, and outlines how the final rulemaking amends specific regulations.

Section 8 93***Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Withdrawal, Federal Register, Jan. 12, 2007***

The FDA announced its withdrawal of the direct final rule on classification regulations for reprocessed SUDs, citing adverse event comments.

Section 9 97***The Medical Device User Fee and Modernization Act of 2002 [amended 2007, see Section 14]***

This law amends the FDCA to improve regulations for devices. The regulation, which states that Congress finds prompt approval is critical, includes definitions, the authority to assess and use device fees, amendments regarding the regulations of devices, such as inspections, penalties and labeling, additional amendments for SUDs in Section 302 and information about premarket notification.

Section 10 151***The Medical Device User Fee and Modernization Act of 2002 — FAQs [amended 2007, see Section 14]***

The FDA answers questions regarding the background of MDUFMA, user fees (including charts), user fee billing issues, third-party inspections, reprocessed SUDs and postmarket surveillance.

Section 11 165
Frequently Asked Questions (FAQs) on the Status of Reprocessed Single-Use Devices (SUDs) that Receive a Not Substantially Equivalent (NSE) Letter, November 2004

This guidance document explains what NSE means and the circumstances and responsibilities regarding such a letter.

Section 12 173
Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA, August 2002

This guidance document provides background about the QS, Blue Book Memorandum K97 regarding changes to existing devices and the enactment of the FDA Modernization Act of 1997 (FDAMA). It also explains methods of sterilization, review procedures for all sterilization methods and additional procedures for 510(k)s.

Section 13 183
Summary of the Medical Device User Fee and Modernization Act of 2002, November 2004

This summary outlines the Medical Device User Fee and Modernization Act of 2002 (amended 2007), highlighting key features of the law, and providing information about review fees, third-party inspections, reprocessed SUDs and additional provisions.

Section 14 213
Title II — Medical Device User Fee Amendments of 2007

This legislation, which is Title II of the FDA Amendments Act of 2007, reauthorized MDUFMA. It became law Sept. 30, 2007. The legislation renews user fees to be paid by device companies. It reduces some application fees and creates new annual fees: an establishment registration fee and a fee for filing periodic reports.

Part III: FDA Action and Strategy

Section 15 239
Executive Summary — Open Meeting: FDA’s Proposed Strategy on Reuse of Single-Use Devices, December 1999

This summary documents the open meeting during which the FDA stated its recognition of the subject’s complexity. The meeting was held to hear what various parties affected by SUDs think about the issue. Speakers raised concerns about SUDs and discussed the general thought that the use of reprocessed SUDs is solely for economic reasons. The FDA’s plan to make risk the primary focus of its regulatory approach also was discussed.

Section 16 251
Center for Devices and Radiological Health Proposed Strategy to Address the Reuse of Medical Devices Currently Labeled, or Otherwise Intended, for Only One Use

This provides background on SUDs and outlines the requirements reprocessed SUDs are subject to in the FDCA and the Code of Federal Regulations.

Section 17 263***Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted, June 2000 GAO report***

The Government Accountability Office (GAO) reviewed SUD reprocessing and outlines its findings about various issues related to reprocessed SUDs, such as cost savings, different types of devices, the frequency of reprocessing, possibility of safely reprocessing, difficulties with the policy and requirements for reprocessors.

Section 18 289***Statement by David Feigal, then CDRH director, before the Senate Committee on Health, Education, Labor and Pensions, June 27, 2000***

Feigal discusses the FDA's reexamination of its SUDs policy, its efforts and available tools to ensure protection of public health. The statement provides background, the scope of reuse, agency involvement in reuse (research, reports of patient injuries and outreach), the FDA's current policy, the agency's proposed strategy regarding enforcement priorities and the steps that were planned, such as final guidance documents, collaboration and phased-in enforcement.

Section 19 301***Reuse of Single-Use Devices, Medical Device Reporting, 1999***

This article provides some background on the reprocessing of SUDs and discusses how the increasing use of SUDs heightened concerns about patient safety and equitable regulations. It provides examples of the FDA's list of frequently reprocessed SUDs and addresses the FDA's current policy and proposed strategy.

Section 20 307***Statement by Daniel Schultz, CDRH director, before the House Committee on Government Reform, Sept. 26, 2006***

Schultz told the committee that the FDA has many tools to ensure safe and effective reprocessed SUDs. He discussed the regulations regarding SUD devices that have been cleared for reprocessing, the changes under MDUFMA (such as the creation of the premarket report), premarket review of reprocessed SUDs, statistics about premarket (510(k)) submissions, compliance activities, postmarket surveillance and ongoing FDA activities.

Part IV: Compliance and Enforcement

Section 21 319***FDA Letter to Hospitals, Enforcement of FDA Requirements on Reprocessing of Single-Use Devices, April 23, 2001***

This letter announced the requirement that hospitals that reprocess SUDs must meet the same requirements as the original product manufacturer. It summarizes the requirements and provides a timetable of enforcement. The letter also outlines the regulatory enforcement actions the FDA is authorized to take for violations.

Section 22 325
FDA Letter to Hospitals, Changes in Enforcement of FDA Requirements on Reprocessing of Single-Use Devices, Sept. 25, 2001

This letter told hospitals of the FDA's extension of its deadline for enforcement of postmarket requirements — medical device reporting, tracking, corrections and recalls, QS and labeling — for hospitals to Aug. 14, 2002. The document outlines the phased-in enforcement of requirements. It also provides examples of completed registration and device listing forms, where to obtain forms and how to complete and submit registration and listing forms.

Section 23 333
Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and Staff, July 2001

This guidance document clarifies the August 2000 document “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.” It includes questions to ask a potential reprocessor. The guidance also covers requirements for reporting an adverse event with a reprocessed SUD, QS and SUD compliance, sterilization and the list of SUDs known to be reprocessed.

Section 24 345
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 Staff, July 2003

This document answers questions regarding registration and listing.

Section 25 353
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, August 2000

This document provides guidance about responsibilities for SUD reprocessors. It includes a background of the use of and regulatory framework surrounding reprocessed SUDs. The guidance document summarizes the FDA's priorities for enforcing premarket submission requirements regarding registration and listing, MDR, device tracking, corrections and removals, QS regulations, labeling and premarket requirements. It also includes comments the agency received after releasing its proposed strategy.

Section 26 375
Reusing Medical Devices Ensuring Safety The Second Time Around, FDA Consumer magazine, September-October 2000

This article covers the FDA's concerns, the MDR system, the CDRH research program that explored the safety of reprocessed SUDs and the August 2000 guidance document on enforcement priorities. It also discusses whether the FDA's approach for enforcement of regulatory requirements is appropriate.

Section 27 381
Guidance Document for Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices, June 1998

This document is intended to clarify the regulatory status of washers and washer-disinfectors for use in processing reusable devices. It discusses when 510(k) submissions are required, which articles are exempt from 510(k) and addresses confusion about unclassified devices.

Section 28 389
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use, April 2001

Hospitals that reprocess SUDs are subject to reporting requirements in 21 CFR Part 803 for adverse events involving SUDs. This guidance document describes MDR requirements and provides guidance on the mandatory MedWatch form.

Section 29 411
Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA, July 2001

Manufacturers engaged in reprocessing devices are subject to regulatory requirements. This guidance document defines label and labeling and includes a question-and-answer section on labeling requirements.

Section 30 423
Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities: FDA Reviewer Guidance, April 1996

This guidance document, which says it will be updated because it was written before the Good Guidance practices, includes recommendations regarding the content of reuse instructions. It also covers premarket notification submissions, reprocessing steps, labeling, documentation of validation and a checklist for reprocessing instruction.
