FDA's Final Policy on Single-Use Devices Reprocessed by Hospitals and Commercial Reprocessors

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Objectives

- Background information on FDA's reuse policy
- SUD Enforcement Guidance - Overview
- Important dates for reprocessors
- Some technical concerns
- Vision for the future

Background information
or “how we got where we are”

- Reuse practiced in hospitals since the late 1970’s

1999

- Apr 5-6 AAMI/FDA co-sponsored meeting on reuse of SUDs

Background continued ...

- Aug 5 Sen. Durbin introduced *Reprocessed Single Use Medical Device Patient Safety Amendments of 1999 (S.1542)*

- Oct 26 Reps. Eshoo & Upton introduced *Reprocessed Single Use Medical Device Patient Safety Act of 1999 (H.R. 3148)*

Background continued ...

- Nov 3 FDA released proposed regulatory strategy
- Nov 10 Satellite teleconference
- Dec 14 Open public meeting

Background continued ...

2000

- Feb 10 House Committee on Commerce hearing on reuse policy

- Feb 11 FDA released 2 draft guidances -
  - *Reprocessing and Reuse of SUDs: Review Prioritization Scheme*

  and

  - *Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals*

Background continued ...

Reprocessing and Reuse of SUDs: Review Prioritization Scheme

- Purpose: to assess the risk of a reprocessed SUD via 2 flowcharts
  - risk of infection
  - risk of reprocessing on SUD's functionality
- SUD rated: *high, moderate, or low*

Background continued ...

Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals

- Purpose: to identify FDA's enforcement priorities and time line based on the level of risk of a reprocessed SUD as determined by the *Review Prioritization Scheme*

Background continued ...

- Jun 27 Senate Committee on Health, Ed., Labor & Pensions' hearing on the General Accounting Office (GAO)'s report *Reprocessing and Reuse of Devices Labeled Single Use*

(www.gao.gov)

Enforcement Priorities for Single-Use Devices Processed by Third Parties and Hospitals

August 14, 2000

- www.fda.gov/cdrh/comp/guidance/1168.pfd

SUD Enforcement Guidance - Overview

Basis of FDA's Authority

- The Federal Food, Drug, and Cosmetic Act
- Title 21 Code of Federal Regulations (CFR)
  Parts 800 to 1299 (*www.gpo.gov)*

SUD Enforcement Guidance continued ...

Underlying principles of FDA's reuse policy:

- Reprocessing is a manufacturing activity.
- FDA will regulate original equipment manufacturers (OEMs) and all SUD reprocessors in the same manner.
- FDA's primary goal is to protect public health by assuring that reprocessed SUDs are as safe and effective as new SUDs.

SUD Enforcement Guidance continued ...

- Does not apply to:
  - Permanent pacemakers;
  - Hemodialyzers;
  - Health care facilities that are not hospitals; or
  - Opened-but-unused SUDs.

SUD Enforcement Guidance continued ...

Working Definitions

- Hospital = an acute health care facility
- SUD = a disposable device; intended to be used on one patient during a single procedure

SUD Enforcement Guidance continued ...

- Reuse = the repeated or multiple use of any medical device (whether labeled SUD or reusable) with reprocessing (cleaning, disinfecting and/or sterilization) between patient uses

SUD Enforcement Guidance continued ...

- Opened-but-unused = a SUD that has not been used on a patient (no contact with blood or bodily fluids) whose sterility has been compromised

SUD Enforcement Guidance continued ...

Regulatory Requirements

1. Registration & Device Listing (21 CFR Part 807)

2. MDR Regulation (21 CFR Part 803)

(www.fda.gov/cdrh/osb/guidance/1334.pdf)

3. Medical Device Tracking (21 CFR Part 821)

SUD Enforcement Guidance continued ...

4. Medical Device Corrections & Removals
   (21 CFR Part 806)

5. Quality System Regulation (21 CFR Part 820)

6. Labeling Requirements (21 CFR Part 801)

7. Premarket Notification & Approval Requirements
   (21 CFR Parts 807 & 814)

Important Dates for SUD Reprocessors

February 14, 2001

=> Deadline for submission of premarket submissions (PMA or 510(k)) for class III SUDs

Important Dates continued ...

August 14, 2001

=> Deadline for hospital reprocessors to comply with non-premarket requirements

=> Deadline for submission of 510(k)s for non-exempt class II SUDs

Important dates continued ...

February 14, 2002

=> Deadline for submission of 510(k)s for non-exempt class I SUDs

Some Technical Concerns

- Control of “raw material”
- Defining specifications
- Identification of changes to OEM devices
- Cleaning, disinfecting, & sterilization procedures
- Functionality of reprocessed SUDs
- Labeling of reprocessed SUDs

Vision for the Future
or “where we need to go”

- Review premarket submissions within regulatory timeframes (180 days for PMAs ; 90 days for 510(k)s)
- Implement an inspection program for hospital reprocessors
- Continue to inspect all commercial reprocessors

FDA Reuse Home Page

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