FDA and the Reuse of Single Use Devices: Policy Moving Forward

Larry Kessler, Sc.D.

Director

Office of Surveillance and Biometrics

CDRH, FDA

Objectives of Presentation

- **Explain background of reuse issue**
- **Describe FDA's proposed change in regulatory strategy**

- *Note that the issue of open but unused devices, a common practice in hospitals, has been taken "off the table": no longer part of FDA's reuse strategy*

FDA's Position Historically

- ***Any Person Engaged in Single Use Device Reprocessing is a "Manufacturer"***
- Reprocessing in Hospitals/Clinics (Compliance Policy Guide 300.500)
- Premarket Submissions Have Not Been Requested

FDA's Position Historically
(continued)

- Requirements of 3rd Party Reprocessing Firms:
  - Device Registration and Listing, 21 CFR, Part 807
  - Good Manufacturing Practice (GMP) Inspection, 21 CFR, Part 820
  - Medical Device Reporting, 21 CFR, Part 803
  - General Labeling Requirements, 21 CFR, Part 801
- Reuse Policy Documents & Correspondence on FDA Web Page (www.fda.gov.reuse)

Why Deal with this Issue

- Identical regulatory controls
  - ***Reprocessing IS manufacturing***
- Public concern
- FDA research shows reprocessing may be feasible, but is difficult and possibly ***dangerous***
  - Minimal evidence of problems does not mean the current practice is safe and effective

Current Guidance and Plans

- Guidance Documents on the WEB
- Finalize approach summer 2000
- Beginning 2001
  - Registration and listing
    - Third Party Reprocessors and Hospitals
  - Premarket submission
  - Hospital inspections via JCAHO
- OEM labeling issues

Changes in Approach

- Procedures already exist for approving the change of a single use device to multiple use
- ***FDA will examine the reuse of single use devices that creates a new single use device***
- Reprocessed SUDs should be labeled the same regardless of who does reprocessing
- FDA still working on submission requirements
- FDA reconsidering “high risk” exempt products

Enforcement Approach

- Third party reprocessors will fall into usual approaches from FDA for manufacturers
- Hospitals may wish to continue to reprocess
  - For reuse of exempt products, hospitals will have to follow general controls (esp. GMP)
  - For non-exempt products, hospitals will have to submit premarket notification or approval
  - FDA partnering with JCAHO to monitor
- Other health care facilities will be considered

Vision for the Future

Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful; don't identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA approach will be risk and science based
- Premarket submissions will be required: projected date Jan 2001
- Horizontal and vertical standards could be useful
- Substantial outreach
- Leverage outside parties, e.g., JCAHO