



Corporate Regulatory Science

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January 7, 2000

The Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: FDA's Proposed Strategy on Reuse of Single Use Devices
[Docket No. 99N-4491]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

SUMMARY

Actions by the FDA to increase the focus and regulatory scrutiny of device reprocessors is a positive change. Many original equipment manufacturers (OEM's) find themselves in tenuous positions between their customers and the activities of reprocessors. We support FDA's proposals to increase the focus on these companies since they appear to operate with a unique set of GMP's. The FDA's focus on this area is justified with respect to patient safety. We further recommend that the FDA continue its constructive set of public exchanges on this subject.

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I. GENERAL REMARKS

- A. The FDA's document on reuse is titled "FDA's Proposed Strategy on Reuse of Single Use Devices." Item #4 in that document is titled: "Consider requesting OEM's to provide information on their labels about risks associated with reuse of SUD's." Our response to this question is as follows:

OEM's should not have to explain why a product is a single use device on their labeling.

OEM's should not have to provide data as to why the product is single use since we follow current regulations which ensure that the product is safely and successfully manufactured.

OEM's should not have to provide instructions for reprocessing or how many times a product can be reprocessed.

Rationale: The suggestion that OEM's should provide new and additional information would create a competitive and financial burden which goes beyond the scope of GMP's. In many instances a single use device being used for the first time will provide optimum performance which might be inhibited by reprocessing after the initial use. Many OEM's have spent years developing and testing devices which are safe and effective and meet current GMP and labeling requirements. Simply giving up this research data to firms who do not have a valid regulatory submission should be reconsidered. Finally, OEM's cannot possibly test for all of the ways a reprocessor may use a single-use device.

- B. Referring to the FDA's document under item #5, A., add the following text as a possible new item #3:

Single-use products that are reprocessed because sterility was breached, after release to the marketplace, by means other than patient contact.

Rationale: Such an instance would be included in the risk organization scheme.

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II. SPECIFIC COMMENTS

- A. Referring to the FDA's teleconference from November 10, 1999, we agree that reprocessors should be required to make formal premarket notification submissions for any reprocessed device. The current regulations for device classes I, II and III should apply to everyone. A special class or second tier of regulations, standards and premarket submissions up to 6 months after reprocessing should not be instituted. This poses a risk to the safety of consumers and it continues the current state of affairs which allows for differences between OEM's and reprocessors. Current standards of acceptance should apply to all parties. As an example, for drug submissions, both new and generic applications are required to follow the same manufacturing regulations for drug applications.
- B. Regulatory scrutiny should focus on independent, for-profit reprocessors who carry out most of the device reprocessing.
- C. Informed consent should be part of a patient's right to know as to whether they are receiving new or reprocessed medical devices as part of their medical treatment.

III. CLOSING COMMENTS

The final promulgation and implementation of any proposed guidance should proceed; however, an industry-wide educational effort should also be considered for the following reasons:

- A. General educational purposes. Due to the cost and broad scope of this proposal, any seminars on the final rule will help everyone concerned. The proposed seminars could be carried out with the support of AAMI, FDLI, AFDO or other scientifically-oriented trade associations.
- B. Publicity. The impact of these possible changes will affect regulatory practices and expectations of manufacturers and other parties. By carrying out these seminars, the Agency can publicize and prepare all concerned for the new requirements.

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III. CLOSING COMMENTS (continued)

C. Clarity. Finally, public seminars will serve to clarify regulatory expectations and interpretations.

Yours truly,



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