



ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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March 19, 2002

Dockets Management Branch (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices [*Docket 01D-0514*]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's consideration of a guidance document on Labeling of Reprocessed Single Use Devices published in the Federal Register on December 20, 2001 at 66 FR 65723. Thank you for the opportunity to provide these comments regarding the use of the original equipment manufacturer (OEM) name and trademark on reprocessed single use devices.

We feel compelling safety factors exist to require the removal of the OEM trademark, name, and OEM references from reprocessed single use devices (SUDs). Such safety factors include product complaint analyses, medical device reporting, issuing safety alerts, conducting recalls, and identification of items subject to safety alerts or recalls.

When an adverse event arises (potential or actual) it is vitally important that the device involved can be identified as an OEM single-use device or as a reprocessed device, and that the correct manufacturer (OEM or reprocessor) is notified of the event, so that an investigation can be conducted and appropriate action can be taken. The inability to properly identify reprocessed devices will result in failures to report adverse events and product complaints to correct manufacturers, thus impacting investigations and trend analyses as required by Quality Systems Regulation (see 21 CFR 820.100 and 820.198). Product complaint trending by OEM and reprocessor manufacturers will be negatively impacted, if product complaints are reported to the incorrect manufacturer. A trend that may be visible if complaints were correctly reported, may take longer to become apparent or may not become apparent at all. This is particularly important for product problems that may be related to material aging, deterioration or fatigue.

Medical device reporting (MDR) is another area where it is necessary for device users to accurately identify medical devices and properly report adverse medical device events. If MDRs are attributed to improperly identified devices or manufacturers, this will hamper FDA's ability to monitor and identify MDR trends to determine if risks exist or if improvements are needed.

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Furthermore, the need to issue safety alerts or conduct recalls makes it ever more important that the correct manufacturer is notified of adverse events and product complaints to prevent the recurrence of identified safety problems. Equally important is the user's ability to correctly identify products subject to safety alerts or recalls. Multiple manufacturer names and/or trademarks associated with a product can make this a confusing task and increases the possibility of erroneous identification.

The safety risks associated with the retention of an OEM trademark on a reprocessed device unit cannot be alleviated by the provision of secondary packaging bearing information about the reprocessor. It is common practice in many health care settings to promptly discard outer packaging, making the association with the reprocessor difficult or impossible to recover. The presence of the OEM trademark is clearly misleading in this scenario.

These safety and quality concerns demonstrate the need for reprocessors to remove, mask or obliterate all OEM trademarks from reprocessed SUDs and to remove from the labeling the OEMs' name and all references to the OEM.

Reprocessors should be required to list their name, address, and telephone number on the reprocessed device labeling. This practice will facilitate the reporting of adverse events and product complaints to the appropriate manufacturer. Furthermore, reprocessed SUD labeling should include a validated reuse life or information in the labeling and on the device, reflecting the number of times the SUD has been reprocessed. Otherwise, SUDs may be reprocessed multiple times under cleaning, disinfection, or sterilization procedures that have only been validated for one time use.

Because FDA is considering allowing reprocessors to market reprocessed SUDs with the OEM name and/or trademark it is ever more important to ensure that reprocessors develop validated test methods and validated cleaning, disinfection, and sterilization conditions consistent with current infection control practices for the qualification and reprocessing of reusable devices. Finally, although FDA has allowed that a predicate device other than the OEM may be relied upon for a determination of substantial equivalence, the OEM device and relevant 510(k) number should be a mandatory component of a reprocessor's 510(k) submission. This allows the FDA to review the OEM 510(k) for any relevant data that may indicate that reuse is not appropriate. The OEM name and trademark connote a certain level of quality, recognized by purchasers and patients. Therefore at a minimum, 510(k) requirements for informative labeling, validated processes, and cross-reference to the OEM device should be put in place and should be subject to FDA review in support of a determination of substantial equivalence.

Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in cursive script that reads "Douglas L. Sporn".

Douglas L. Sporn
Divisional Vice President
Corporate Regulatory Affairs, Abbott Laboratories

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