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Dockets Management Branch (HFA-305)
Food and Drug Administration
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Subject: Comments on the Contents for Drafting a Guidance Document on Labeling of Reprocessed Single Use Devices – Docket No. 01D-0514; (Federal Register, December 20, 2001 [66 FR 65723])

Dear Sir or Madam:

On December 20, 2001 in the Federal Register, FDA requested comments and suggestions on the contents of a guidance that the agency is considering drafting on the labeling of reprocessed single use devices (SUDs) with respect to the name of the original equipment manufacturer (OEM) and the remanufacturer (i.e., reprocessor). Alcon Research, Ltd. is submitting the following comments based upon dialogue within Alcon among the manufacturing/packaging, marketing, labeling, product safety, and regulatory communities.

- Manufacturer's Responsibilities Per the Quality Systems Requirements (QSR)

It is the responsibility of a manufacturer to conduct all QSR related activities. According to 21 CFR Part 820.3, the definition of a manufacturer includes a reprocessor. Once an OEM's product is reprocessed by a third party reprocessor, the device is no longer the product of the OEM, but instead the third party reprocessor is the manufacturer of record. The device itself becomes an entirely new device owned by the third party. This means the third party reprocessor is now responsible for complaint handling, Medical Device Reporting (MDR), and Corrections and Removal for that specific product.

- Clarity of Product Manufacturer/Reprocessor on Labeling

Alcon believes product manufacturer identification to be key in the fulfillment of regulatory requirements regarding medical devices, such as complaint handling, MDRs, and Removal and Correction/Recall actions. To this end, it must be obvious to the user that the reprocessor has reprocessed a single-use OEM product and is responsible for the device by the labeling. There should be no confusion to the user as to who is now the "Manufacturer" (i.e. the "Reprocessor"). Furthermore, in accordance with 502(b) of the Food, Drug and Cosmetic Act, the reprocessor of a SUD should be required to include, in a conspicuous manner on the immediate container of the device and on the outside container or wrapper of a retail package, the name and place of its business.

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To accomplish this task, it is important that the third party reprocessor or manufacturer provide the necessary information for conducting these duties in the same manner as the OEM, as required by 21 CFR 801 Labeling.

Key elements specific to the manufacturer to be addressed include:

- Name of Manufacturer, and
- Manufacturer Contact Information.

According to 21 CFR 801.1(a), "The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor."

The inclusion of the manufacturer (reprocessor) name allows the user/patient to readily identify the manufacturer, facilitating the communication of potentially serious product-related information back to the manufacturer in a timely manner.

In order to assure the proper manufacturer is contacted, the following suggestions are offered:

- a) Reprocessors shall obliterate, overlabel, or otherwise render the OEM contact information and trademark (name, address, etc.) on the product, packaging, labeling, or other literature and promotional materials unreadable prior to such product or labeling being introduced into the market, thus removing all connection of the newly reprocessed device to the OEM device.
- b) The reprocessor shall replace the OEM contact information with contact information for the reprocessor of the device. Accompanying labeling shall bear a statement to the effect of, "This is a reprocessed device. Contact <insert reprocessor information> for complaints and adverse event reporting" or "Note: <Reprocessor name> has reprocessed this device and is now solely responsible for all product issues."
- c) The reprocessor shall replace or include specific information on accompanying labeling, indicating the appropriate reprocessor contact information and any specific instructions for use, warnings, risks associated with reuse, etc. associated with the reprocessed device.

This information should be displayed in a manner that is obvious to the user, and failure to do so would violate 21 CFR Sections 801.1 and 801.6 as making false representations with respect to the OEM manufacturer identification. Further, in this case, the reprocessor should be considered responsible for rendering the new device misbranded under section 201(n) of the Act.

- Additional Reprocessed SUD Product Information to Consider

Alcon believes the following information should be included on the reprocessed product's labeling or be readily available when reprocessing of a SUD is performed:

- a) Validation information as to the number of times the SUD has been validated for reprocessing,
- b) The number of times this specific SUD has been processed,

- c) A warning against additional reprocessing of the SUD beyond its validated limit, and
- d) In the case of non-sterile devices, provide at least one validated method by which sterilization may be accomplished.

To address the issue of tracking for both reporting and liability purposes, an identification system (e.g. adhesive label) should be provided with each reprocessed device to provide a means for the user to 'tag' patient records that a reprocessed device was used in this procedure. This would also assist in proper identification and reporting where a mix of both reprocessed and OEM devices are used in a procedure or series of procedures.

A specific method for the new device to track the above information should be employed. Examples include, but are not limited to:

- a) Physical tagging and tracking, such as etching, cable tag, marker or adhesive label, and
- b) Logical tagging and tracking of the product via a permanent identification means.

Additionally, in accordance with 21 CFR 801.6, FDA should prohibit reproprocessors from marketing reprocessed OEM devices by indicating or inferring, either written or verbally, the reprocessed device was originally produced by a specific company. Such claims would render the device misbranded under section 201(n) of the Act. For example: Reprocessor "x" markets a reprocessed device by claiming it was originally manufactured by OEM company "y". This could be perceived as the OEM still having some degree of responsibility for the 'new' (reprocessed) device. As stated earlier, upon reprocessing the reprocessor assumes all responsibility and liability for the reprocessed device.

Summary of Alcon's Position

In summation, Alcon believes that the following key points should be considered by FDA when drafting a guidance document on the labeling of reprocessed single use devices:

- Reprocessors of SUDs are considered manufacturers per 21 CFR Part 820.3 and must be responsible for all applicable duties required of a device manufacturer, such as complaint handling, MDRs, and Corrections and Removal for the product.
- The reprocessor's name, place of business, and contact information should be required on all reprocessed SUD labeling. Further, all references to the OEM (including name, contact information, trademark, packaging, labeling, promotional materials, etc.) should be obliterated, overlabeled, or made unreadable on reprocessed SUDs to avoid confusing the end-user as to which party has regulatory and legal responsibility for marketing the reprocessed device.
- Additional information regarding the reprocessed SUD should be readily available from the reprocessor. Such information includes, but is not limited to,

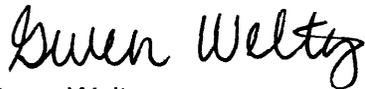
the validation information of a reprocessed SUD, the number of times a specific SUD has been reprocessed, warnings against additional reprocessing of SUDs beyond their validated limits, and the access to validated methods by which sterilization may be accomplished on non-sterile devices.

- Reprocessed SUDs should have an associated identification system in order to track which device was used with a particular patient.
- Reprocessors should be prohibited from mentioning or alluding to the OEM when marketing reprocessed SUDs.

Although Alcon disagrees with the practice of reprocessing single use devices, Alcon hopes that this industry insight is helpful to FDA in drafting the guidance on labeling requirements of reprocessed single-use devices. Further, Alcon appreciates the opportunity to provide these written comments in anticipation of future direction to regulated industry on this matter.

Please contact me should you have any questions regarding these comments at (817) 551-4774.

Best regards,



Gwen Welty
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Alcon Research, Ltd.

