NOTE: Some enforcement dates in this document have been extended as explained in the FDA Talk Paper of August 16, 2001, available at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html. For additional information about the enforcement extensions, see Letter to Hospitals (September 25, 2001), available at http://www.fda.gov/cdrh/reuse/reuse-letter-092501.html.

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA

Document issued on: July 30, 2001

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Larry D. Spears at 301-594-4646 or by electronic mail at lxs@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1392.pdf or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1392 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Introduction

The "Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals: Final Guidance for Industry and FDA" document provides guidance to third party and hospital reprocessors about their responsibility as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third Party and hospital reprocessors of single-use devices are subject to all the regulatory requirements currently applicable to original device manufacturers. Further information can be found in Labeling-Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/cdrh/dsma/470.pdf.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

II. Definitions

For purposes of this guidance, FDA has defined the following terms:

Hospital: A hospital is an acute care facility

Labels and labeling: Sections 201(k) and (m) of the Act define the terms "label" and "labeling."

A "label" is a "display of written, printed, or graphic matter upon the immediate container of any device." Any information required on the immediate container of a device must also appear on the outside container or wrapper, if any, of the retail package for the device, or be easily legible through the outside container or wrapper. Section 201(k) of the Act; 21 CFR 1.3(b).

"Labeling" is defined as: "all labels and other written, printed, or graphic matter"

(1) Upon any device or any of its containers or wrappers, or

(2) Accompanying such device.

Section 201(m) of the Act; 21CFR 1.3(a).

Labeling is a broad term that includes the label and other written, printed, or graphic matter accompanying a device. For example, labeling would include device inserts, leaflets used to promote the device, text written on the box, and the immediate container for the device. Certain provisions of the Act apply only to the "label" of the device, (e.g. 21 CFR 801.1) and other provisions related to the device's "labeling."

Single-use device: A single-use device, also referred to as a disposable device, intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. The labeling may or may not identify the device as single use or disposable and does not include instructions for reprocessing.

Third party reprocessor: Party who reprocesses used SUD's for another party.

Premarket Requirements: These requirements relate to submissions that contain safety and effectiveness information that FDA reviews prior to marketing a device. The two types of premarket submissions that may be required before you reprocess a SUD are: (1) an application for premarket approval (PMA); see section 515(a) of the Act, and (2) a premarket notification submission (510(k). See section 510(k) of the Act.

Reuse: The repeated use or multiple use of any medical device including devices intended for reuse or single-use, with reprocessing (cleaning, disinfection or sterilization) between uses.

Reprocessing: Reprocessing includes all the steps performed to make a contaminated reusable or single-use device ready for patient use. The steps may include cleaning, functional testing, repackaging, relabeling, disinfection or sterilization.

III. WHO DOES THIS GUIDANCE COVER?

This guidance applies to hospitals and third parties that reprocess single-use devices (SUD's).

IV. WHAT ARE THE LABELING REQUIREMENTS?

There are several labeling requirements that apply to reprocessed SUD's. The questions and answers below help to explain labeling requirements that apply to single use devices that are reprocessed for reuse in humans.

1. Do SUDs reprocessed by hospitals and third parties have to meet FDA labeling requirements?

Yes. All devices, including reprocessed SUDs, need to meet the labeling requirements of the Federal Food, Drug, and Cosmetic Act (the Act). A failure to meet FDA's statutory and regulatory labeling requirements will result in a device being misbranded under the Act. See section 502 of the Act.

2. What are your labeling responsibilities if you reprocess, or use, or ship, or sell SUD's?

Certain labeling responsibilities apply to persons who reprocess, use, ship, or sell reprocessed SUD's, regardless of whether the person is the one who is required to submit a premarket submission (510(k)) or premarket approval application (PMA), and regardless of whether the device is exempt from premarket requirements.

The following scenarios will help describe the labeling responsibilities that are independent of premarket requirements:

(1) If a hospital reprocesses a SUD, the hospital is responsible for ensuring that the device complies with all applicable FDA labeling requirements, even if the device is exempt from the premarket requirements. If the hospital does not ensure the device complies with FDA labeling requirements, the device is misbranded, and the hospital may be considered responsible for causing the misbranding of the device in violation of section 301(k) of the Act.

(2) If a hospital ships a SUD to a third party for reprocessing, the hospital needs to ensure that the device is in compliance with labeling requirements before the device is sent to the third party, so that the device is not considered misbranded. See section 301(a) of the Act. A

hospital, however, may label devices that are shipped for further processing in a manner that exempts the devices from labeling requirements. (See Response to question 12 for possible exemption from certain labeling requirements).

(3) If a hospital receives reprocessed SUD devices from a third party that are misbranded, the hospital may be considered responsible for receiving misbranded devices. See section 301(c) of the Act.

(4) If a third party reprocessor receives reprocessed SUD devices from a hospital that are misbranded, the third party reprocessor may be considered responsible for receiving misbranded devices. See section 301(c) of the Act.

(5) If a third party reprocessor ships devices to a hospital that do not comply with labeling requirements, the third party reprocessor may be considered responsible for shipping misbranded devices. See section 301(a) of the Act.

In summary, you should ensure that all reprocessed SUD's that you receive, use, ship, or sell are properly labeled in accordance with FDA regulations. Failure to comply with FDA labeling requirements will cause a device to be "misbranded" and, therefore, in violation of FDA law. Section 502 of the Act.

3. If I submit a premarket submission or application for a reprocessed SUD, what labeling do I have to submit to FDA for review?

For devices that require premarket clearance or approval, FDA reviews the proposed label for the device before FDA makes the decision of whether the device can be commercially distributed. The persons required to submit the marketing submissions are responsible for the label.

4. What are the general labeling requirements that apply to reprocessed SUD devices?

To satisfy FDA's general device labeling requirements, the labeling of a reprocessed SUD must:

a. include the name and place of business of the manufacturer, packer, or distributor (section 502(b) of the Act; 21 CFR 801.1).

b. bear the common or usual name of the device (Section 502(e)(2) of the Act).

c. state the quantity of contents (Section 502(b)(2)).

d. include adequate directions for use (section 502(f)(1) of the Act; 21 CFR 801.5) or qualify for an exemption from adequate directions for use (the prescription device exemption, 21 CFR 801.109).

e. include adequate warnings (section 502(f)(2) of the Act).

f. not be false or misleading (section 502(a) of the Act).

g. give adequate prominence to information required to appear on the label (section 502(c) of the Act; 21 CFR 801.15).

   Required labeling information needs to be displayed in a manner that is obvious to the reader. Section 801.15 describes specific requirements that relate to how the labeling information must be displayed.

h. appear in English with the exception of devices distributed solely within Puerto Rico or a US territory where the predominant language is not English, or devices solely distributed outside the United States that comply with FDA's export requirements (21 CFR 801.15(c)).

5. What information has to appear on the device's label?

FDA regulations require that certain information be on a device's label if the device is in a package. Specifically, section 801.1 of FDA's regulations, and Section 201(k) of the Act require that the label on the immediate container of the device, and any outside container or wrapper of a retail package include in a conspicuous manner, the name and place of business of the manufacturer, packer, or distributor. These label requirements apply to Third Party and hospital reprocessors of single-use devices.

The requirement in section 801.1 to include the name of the manufacturer, packer, distributor, or reprocessor will be met, such as in the case of a corporation, if the label includes the actual corporate name together with the name of the particular division of the corporation. Abbreviations for "Company" and "Incorporated", etc. may be used. "The " may be omitted. In the case of an individual, partnership, or association, the name under which the business operates must be used.

The statement of the place of business must include the street address, city, state, and zip code. However, FDA regulations do permit exceptions to the requirement to include the street address and zip code on the label in certain limited circumstances. (21 CFR 801.1(d) and (e)).

If a person manufactures, packs, distributes or reprocesses a device at a place other than his principal place of business, the label may state the principal place of business instead of the actual place the device was manufactured, packed, or distributed, unless doing so would be misleading.

6. What name should be designated on the SUD's label as the manufacturer?

Persons who reprocess single use devices are engaged in manufacturing activities. See e.g. 21 CFR 803.3(o); 806.2(g); 807.3(d); 820.3(o); 821.3(c). Accordingly, the name of the reprocessor should

appear on the label as the manufacturer of any SUD device that it reprocesses. This information helps to identify the firm or business that is responsible for introducing the SUD into commerce.

The following examples describe who should be listed as the manufacturer in two common situations:

a. If a SUD is reprocessed by the hospital, the hospital is engaged in manufacturing activities, therefore the hospital should state its name, and place of business on the device's label.

b. If a SUD is reprocessed by a third party, the third party reprocessor is engaged in manufacturing activities, therefore the third party reprocessor should state its name, and place of business on the device's label.

7. What does it mean for labeling to bear adequate directions for use?

Adequate directions for use means directions that would allow a layperson (i.e., a person who is not a health professional) to use a device safely and for the purposes for which it is intended to be used. FDA regulations at 21 CFR 801.5 set out some factors that are relevant to meeting this requirement.

Some devices are exempt from the requirement that their labeling include adequate directions for use by a layperson. One such exemption applies to prescription devices provided they meet the prescription device labeling requirements and certain other requirements outlined in FDA's regulations. (21 CFR 801.109).

Almost all reprocessed SUD devices are prescription devices and therefore will need to comply with the prescription device requirements in order to be exempt from the requirements for adequate directions for use by a layperson. The prescription device exemption and other exemptions from the adequate directions for use requirement are explained below (see question 8, 12, and 13 for exemptions to adequate directions for use), and in FDA regulations, 21 CFR 801.109.

8. What are the labeling requirements for prescription devices?

As stated above, the term "adequate directions for use" is defined as directions that would allow a layperson to safely use the device (21 CFR 801.5). Because it is not possible to write adequate directions for the safe use of a prescription device by a layperson, prescription devices are exempt from this requirement if certain conditions are met.

One of those conditions is that the labeling must meet the prescription device labeling requirements. These requirements are designed to ensure that a practitioner licensed by law to administer the devices can use them safely and for their intended purpose.

FDA regulations at section 21 CFR 801.109(b) require that the label of prescription device (other than a surgical instrument) include:

- The statement “Caution: Federal law restricts this device to sale by or on the order of….(e.g., a physician),"; and[1]

- the method of its application or use.

Section 801.109 further requires that the labeling on or within the package from which the prescription device is dispensed include, among other things, the following information:

- indications

- contraindications

- directions for use

- any relevant precautions, hazards, warnings, and other information---unless providing this information is unnecessary because it is already commonly known to practitioners who are licensed to use the device

Other conditions that must be met in order for a prescription device to be exempt from the "adequate directions for use" requirement relate to possession and sale of the device rather than to the device's labeling. These other requirements, however, are beyond the scope of this document. (See 21 CFR 801.109(a)).

In addition to the labeling requirements of 801.109, prescription devices must meet other labeling requirements described in this guidance and in FDA's labeling regulations.

9. Do over-the-counter (OTC) devices have to meet any specific labeling requirements, in addition to the general labeling requirements?

Yes, over-the-counter devices must meet certain specific OTC labeling requirements relating to the principal display panel, the statement of identity, and the declaration of net quantity of contents. These requirements are described in detail in 21 CFR 801.60, 801.61, and 801.62.

---

1 FDA does not intend to enforce the requirement for the full textual prescription statement under 21 CFR 801.109(a) if the product labeling states, "Rx Only" instead of quoting the text required by the regulation. See FDA's prescription labeling guidance, which is available on the Internet at http:/www.fda.gov/cdrh/comp/rxlabeling.pdf, or request a fax copy by telephone at 1-800-899-0381 and specify number 1150 when prompted for a shelf number.

10. If I reprocess another manufacturer's device that was intended for single use, can I use the previous manufacturer's labeling?

FDA regulations would require that some parts of the previous manufacturer's labeling be modified. For example, under section 801.1, the device needs to be have a label with the name and address of the reprocessor of the SUD. See question 6 above.

Each over the counter device must have labeling that carries adequate directions for use, as described in 21 CFR 801.5, or if it is a prescription device, other information about how to use the product, as described in 21 CFR 801.109 and in response to question 8.

If your device is the same in all respects to the device as manufactured by the previous manufacturer, the way in which you describe the directions for use for the device in your labeling may be similar to the previous manufacturer's labeling. If you have changed the operation, design, intended use, or any other aspect of the device, the directions for use may have to be different from that of the previous manufacturer's labeling. The changes in the directions for use may be required in order for FDA to determine that the labeling contains adequate directions for use (21 CFR 801.5), or sufficient information to satisfy applicable prescription device requirements, as described in 21 CFR 801.109.

In addition, you must ensure that your labeling is not false and misleading. This would include making sure that any statements that you make in the labeling that are similar to the previous manufacturer's, are still truthful and not misleading with respect to the reprocessed SUD. For example, if you have made changes to the previous manufacturer's device specifications, a labeling statement that represents the out-dated specifications of the device's previous manufacturer would be false.

11. If I copy some of the previous manufacturer's labeling, is it a copyright or trademark violation?

FDA does not have authority or the expertise to provide advice on what constitutes copyright or trademark violations. You should consult with your own legal counsel with expertise on these types of matters.

12. If a hospital ships a device to a third party for reprocessing, does the device need to be labeled with adequate directions for use or have prescription labeling?

Devices need to comply with these requirements, unless there is an applicable exception. Shipments of devices that are intended to be reprocessed by another entity are exempted from adequate directions for use requirements if their label bears the statement "Caution: For manufacturing, processing, or repacking." 21 CFR 801.122. This exemption would also apply to prescription devices that are labeled in this manner. Accordingly, a hospital that ships devices to a third party reprocessor could be exempt from adequate directions for use and prescription labeling requirements by labeling the device as

described above.

13. If a third party reprocessor ships a device back to a hospital, does it need to be labeled?

Yes, unless the shipment falls within one of the exemptions specified in the regulations, a third party reprocessor shipping devices to a hospital needs to comply with all the labeling requirements. Otherwise the devices would be misbranded.