



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 17 2001

0733 01 OCT 24 11:17

Thomas Scarlett, Esq.  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N.W.  
Suite 1200  
Washington, D.C. 20005-5929

Re: Docket #01P-0148

*Tom*  
Dear Mr. ~~Scarlett~~:

This is in response to your citizen petition on behalf of the Association of Disposable Device Manufacturers (ADDM), dated March 22, 2001, requesting that the Food and Drug Administration (FDA): (1) require reproprocessors of single use devices (hereinafter referred to as reprocessed devices) to remove the original equipment manufacturer (OEM) trademark from the devices and any references to the OEM in the label of devices; (2) take actions to identify and enforce this requirement; and (3) refuse to approve premarket submissions unless the applicant represents that the device will meet this requirement.

Your requests are based on your assertions that representations about an OEM on a reprocessed device would result in the misbranding of the device under several different provisions of the Federal Food, Drug, and Cosmetic Act (the Act). Our Office of Chief Counsel has considered the legal arguments supporting your petition and the results of their analysis are included in the discussion below. FDA agrees that certain representations with respect to the OEM on a reprocessed device may be misleading. However, for the reasons discussed below, FDA is denying your petition because the agency believes that any misleading implications from representations concerning the OEM can be remedied by the disclosure of additional facts about the reproprocessor.

Misbranding under section 502(b)<sup>1</sup> of the Act

**OIP-0148**

**PDN 1**

<sup>1</sup> All cited provisions of the Act are in 21 U.S.C. §§ 321 et seq.

You allege that a reprocessed device that bears the name of both the reprocessor and the OEM violates section 502(b) of the Act. Section 502(b) of the Act states that a device is deemed misbranded "unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor..." Section 502(b)'s implementing regulation for devices, 21 C.F.R. § 801.1, requires the "label of a device in package form" to "specify conspicuously the name and place of business of the manufacturer, packer, or distributor." You allege that the device regulation does not accommodate the identification of a raw material source on the label of a finished product.

The language in 21 CFR § 801.1 only addresses the information that must be included on the label. It does not address information that cannot be included on the label. Accordingly, FDA believes that this implementing regulation of 502(b) should not be interpreted to proscribe references to OEMs.<sup>2</sup> Therefore, if a reprocessor's, distributor's, or packer's name and address are stated conspicuously on the label, the label complies with 21 C.F.R. 801.1, regardless of whether references to the OEM appear.

FDA agrees that references on a label to the OEM may render the content as a whole misleading under section 502(a) of the Act under certain circumstances if the references mislead users or the FDA as to the identity of the manufacturer responsible for the device. FDA's analysis of whether representations about an OEM may misbrand a reprocessed device under section 502(a) of the Act is discussed in detail below.

---

<sup>2</sup> You also note in your petition that the drug regulation, 21 C.F.R. § 201.1(h), that corresponds to the device regulation, 21 C.F.R. § 801.1, specifically prohibits the naming of any person other than the manufacturer, packer, or distributor. You believe that the device provision, which contains no such specific prohibition, should be interpreted in the same manner as the drug provision. Since your petition is relevant only to devices, FDA is not addressing whether labeling violations would exist if the drug provisions applied to devices. FDA notes, however, that the fact the drug provision contains a specific prohibition against naming parties other than the manufacturer, packer, or distributor, and the device provision contains no such prohibition, would appear to support a conclusion that the device provision does not prohibit naming additional parties.

Misbranding under section 502(a) of the Act

You allege that reprocessed devices that have labeling that makes representations about an OEM, including the use of the OEM trademark or trade name, would misbrand the device under section 502(a) of the Act, and an implementing regulation, 21 C.F.R. § 801.6.

You maintain that such representations also would thwart other provisions related to prohibitions against counterfeiting and imitating drugs, and trademark and trade name infringement that serve the same purposes as the Act's misbranding provisions that apply to devices.<sup>3</sup>

Namely, you allege that a reprocessor will violate these provisions if it uses any representation with respect to the OEM of a device because the user will incorrectly infer that:

- reprocessed devices have the same quality as the OEM's device, when in fact they are "inferior" to the OEM product because reprocessed devices bear the risk of contamination, and may be more likely to fail;
- the OEM has made a determination that the device is fit for reprocessing;
- the OEM is a direct and cooperative participant in the manufacture of the reprocessed device;

---

<sup>3</sup> Specifically, although you do not request FDA to regulate reprocessed devices' labeling under these provisions, you allege that labeling representations about OEMs on reprocessed devices would run counter to the purposes of other related provisions that prohibit trademark infringement under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and provisions under the Act related solely to drugs prohibiting counterfeiting and imitation -- sections 201(g)(2) and 502(i)(2) of the Act. FDA does not specifically address your arguments under these provisions since they are not germane to your request. FDA notes, however, that to the extent the Act's device misbranding provisions under sections 502(a) and (b) are related to the Act's drug provisions and the Lanham Act's trademark provisions, the agency's reasoning in its response to your arguments under section 502(a) would apply to drug and trademark provisions.

- MDR reports should be sent to the OEM, not the reprocessor.

You also allege that any labeling on a reprocessed product that makes representations about an OEM could only avoid being misleading if it revealed facts that you consider to be "material" such as:

- the source of the product is the hospital, not the OEM;
- if applicable, the reprocessed device is not substantially equivalent to the OEM's device;
- the OEM recommends against reprocessing; and
- the OEM has made no determination that the device is fit for reprocessing.

With one exception described below, FDA does not agree that the failure to provide the information above would render the product misbranded under section 502(a) of the Act or its implementing regulation, 21 CFR § 801.6.

Section 502(a) of the Act states that a device is deemed misbranded if "its labeling is false or misleading in any particular." Section 801.6 of Title 21 C.F.R. states, "[a]mong representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device ...."

Section 201(n) of the Act states that in determining whether labeling is misleading:

...there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling ... fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling ... relates under the conditions of use prescribed in the labeling... or under such conditions of use as are customary or usual.

Page 5 - Thomas Scarlett, Esq.

Accordingly, if a failure to disclose information is to be considered misleading under the Act, the information that is not disclosed must be "material."

Your petition emphasizes your conclusion that representations related to the OEM are misleading because the user would mistakenly believe that the quality of a reprocessed device and the original device are the same. Your reasoning rests on a presumption that the quality of all reprocessed devices are inferior to the original device's quality. Although you do not explain fully, FDA assumes that because you presume that the quality of a reprocessed device is inferior to an original device, you also believe that the following information is material: (1) the source of the product is the hospital, not the OEM; (2) the OEM has not been a direct and cooperative participant in the manufacture of a reprocessed device; and (3) that a reprocessed device may not be substantially equivalent to the OEM's device.

As stated above, section 201(n), in relevant part, requires labeling to disclose only facts that are "material." You have not presented evidence to support a categorical conclusion that the quality of a reprocessed device that meets the same requirements of the Act as an OEM's device is inferior. Accordingly, the quality of the reprocessed device, and information you presume is related to quality, such as information about the source and substantial equivalence, would not be a material fact that the labeling would need to disclose. See Alliance for Bio-Integrity v. Shalala, 116 F.Supp. 166, 179 (D.C. 2000) (factual predicate to labeling requirement for different products is a determination that the products differ materially); Stauber v. Shalala, 895 F.Supp. 1178, 1193 (W.D. Wisc. 1995).

Similarly, we do not agree that the fact that the OEM has not made a determination that the device is fit for reprocessing, or recommends against reprocessing, is a material fact that would justify a labeling requirement. A single use label on an OEM's device represents the OEM's decision to label the product that way, and to seek FDA clearance or approval for only one use. As you know, the premarket requirements for devices do not require the OEM who labels a product for single use to provide data that establishes the device is not safe and effective for an additional use. An OEM's determination about the fitness of a reprocessor's device is not relevant if a reprocessed device

Page 6 - Thomas Scarlett, Esq.

meets the Act's safety and effectiveness requirements. Accordingly, we do not believe that an OEM's determinations provide a basis for labeling requirements for reprocessed devices.

FDA, however, does believe that representations concerning the OEM may be misleading unless the reprocessor of a single use device provides additional information that would indicate that the reprocessor is the manufacturer responsible for product problems. As you note in your petition, hospitals and other user facilities must alert FDA or the manufacturer whenever there is information that "reasonably suggests that a device has or may have caused or contributed to the death ...[or] serious injury to a patient..." 21 C.F.R. § 803.30(a). Moreover, the user or FDA may need to know the identity of the manufacturer, not only for the purposes of reporting adverse events to FDA, but to assure that the responsible manufacturer or FDA can investigate the problem to determine if additional steps should be taken, including distribution of safety information to the users, or product recalls. Accordingly, FDA believes that when a reprocessed product's labeling makes representations that suggest the OEM should be notified of product problems, additional information that provides the correct identity of the reprocessor as the remanufacturer who is responsible for adverse event reporting, recalls, or other corrective actions, is "material" information within the meaning of section 201(n) of the Act because such information is necessary to enable FDA's postmarket reporting procedures under section 519 of the Act to function effectively.

For the reasons discussed above, therefore, FDA does not agree that representations about the OEM on reprocessed devices are inherently misleading. Rather, FDA believes that any potentially misleading implications from representations about OEMs can and should be remedied by the disclosure of additional information described above. Accordingly, FDA denies your request to require reproprocessors of single use devices to remove any references to OEMs from their labels, or to take any actions to enforce such a ban.

We intend to publish a guidance document in the near future that will recommend more specific language and direction to regulated industry on this matter. We also intend to conduct educational outreach to inform industry and users as to our current thinking

Page 7 - Thomas Scarlett, Esq.

regarding the labeling requirements applicable to reprocessed single-use devices.

If you have any questions, please contact Larry Spears at (301) 594-4692.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Kahan".

Linda S. Kahan  
Deputy Director  
Center for Devices and  
Radiological Health