

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 01D-0514]

Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing an opportunity for interested persons to submit comments and suggestions on the contents of a guidance document that FDA 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). FDA is publishing this notice in order to gather informed comment before drafting the guidance.

DATES: Submit written or electronic comments or suggestions by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to [http:// www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments).

FOR FURTHER INFORMATION CONTACT: Larry Spears, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4692.

SUPPLEMENTARY INFORMATION:

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I. Background

In a citizen petition, dated March 22, 2001, the Association of Disposable Device Manufacturers (ADDM) requested that FDA: (1) Require reproprocessors of SUDs (hereinafter referred to as reprocessed devices) to remove the 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.

On September 17, 2001, FDA issued a response to this petition. FDA denied the petition because FDA believed that misleading implications from representations concerning the OEM may be remedied by the disclosure of additional facts about the remanufacturer. Specifically, FDA stated:

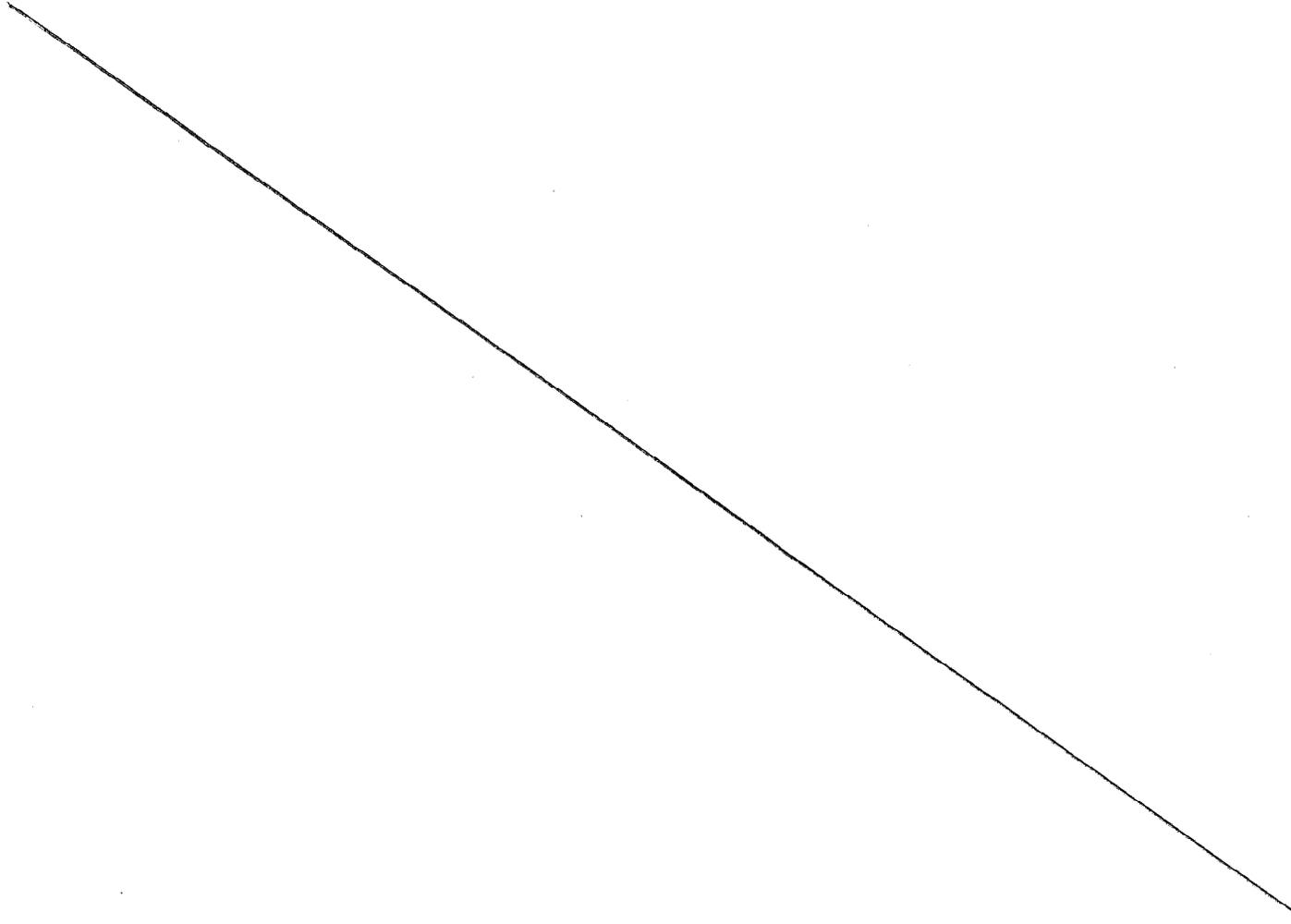
FDA, however, does believe that representations concerning the OEM may be misleading unless the reproprocessor of a single use device provides additional information that would indicate that the reproprocessor is the manufacturer responsible for product problems. As you note in your petition, hospitals 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 reproprocessor 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.

In the response to the petition, FDA also said that it would publish a guidance document that will recommend more specific language and direction to regulated industry on this matter. Before it develops this guidance document, FDA is inviting interested persons to submit comments and suggestions on the contents of such a guidance.

The ADDM petition and FDA's response are available from the Dockets Management Branch (address above). Please reference Docket No. 01P-0148.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments or suggestions regarding this issue by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except



that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/28/01

November 28, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
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[FR Doc. 01-???) Filed ??-??-01; 8:45 am]

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Linda S. Kahan