

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0232]

*DMB*

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**Medical Devices Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices." This draft guidance document provides premarket guidance to the medical device industry, including third party and hospital reprocessors, and to Center for Devices and Radiological Health (CDRH) staff, who are responsible for the premarket evaluation of submissions for reprocessed single-use devices (SUDs) or related enforcement activities. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled, "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Tim Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 14, 2000 (65 FR 49583), FDA published a final guidance entitled “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals” (“the Enforcement Priorities document”). The Enforcement Priorities document provides guidance to third parties and hospital reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for SUDs under the Federal Food, Drug, and Cosmetic Act. This draft guidance document entitled “Premarket Guidance: Reprocessing and Reuse of Single-Use Devices,” expands upon the summary premarket information in the Enforcement Priorities document.

**II. Significance of Guidance**

This draft guidance document represents the agency’s current thinking on policies and recommendations regarding premarket regulatory and technical issues for reprocessed SUDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

### III. Electronic Access

In order to receive "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices" 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 (1331) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

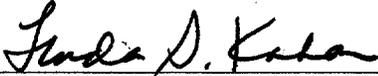
Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

### IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by [*insert date 90 days from date of publication in the Federal Register*]. Submit two copies of any comments, 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. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/22/01  
May 22, 2001.



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

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