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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	J. W. W. W.

Food and Drug Administration

[Docket No. 00D-0053]

**Draft Guidance on Reprocessing and Reuse of Single-Use Devices: Risk  
Categorization Scheme; 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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme." This draft guidance is not final nor is it in effect at this time. This document is intended to provide draft guidance for categorizing the risks posed by single-use devices (SUD's) that are reprocessed and/or reused. FDA may use this scheme to set enforcement priorities for regulation of reprocessed and/or reused SUD's.

**DATES:** Submit written comments concerning this draft guidance by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme" to the Division of Small Manufacturers Assistance (HFZ-220),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.

Submit written comments concerning this draft guidance to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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Comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Timothy A. 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**

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug and Cosmetic Act. On May 5 and 6, 1999, FDA and the Association for the Advancement of Medical Instrumentation cosponsored a conference on reuse of single-use devices to help examine policy alternatives regarding the practice of reuse. As a result of that meeting, FDA made the draft guidance entitled "FDA's Proposed Strategy on Reuse of Single-Use Devices" available on November 3, 1999. Risk categorization of SUD's was one topic of discussion at an open meeting held by FDA on December 14, 1999. This document was the basis for the discussion at that meeting and is now being made more widely available for public comment. FDA expects to issue an updated draft of this guidance shortly and will also make that draft available for public comment.

**II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on the categorization of risk for SUD's. 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, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR

8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

### III. Electronic Access

In order to receive the draft guidance entitled "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1156 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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. Updated on a regular basis, the CDRH home page includes "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme," 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>. "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme" will be available at <http://www.fda.gov/cdrh/Reuse>.

### IV. Comments

Interested persons may, on or before [*insert date 90 days from date of publication in the Federal Register*], submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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. The 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: 1/23/00  
January 23, 2000

*Linda S. Kahan*

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

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL  
*Jan Windsor*

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