

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0193]

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Certifier	<u>TNJ</u>

**Medical Devices Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers." This draft guidance document provides specific recommendations on data and information medical device manufacturers should submit in premarket notifications (510(k)s) for biological indicators intended to monitor sterilizers used in health care facilities. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug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 Submit written comments concerning this draft guidance to the Dockets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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA regulates biological indicators intended to monitor sterilizers used in health care facilities as class II medical devices, requiring premarket notification (510(k)). The effective performance of sterilizers used in health care facilities is important to prevent nosocomial infections. Biological indicators provide users with information on the effectiveness of the sterilization process. This draft guidance document recommends the kind of data and information you should submit in a 510(k) for these devices. The use of comprehensive, scientifically sound review criteria helps ensure the safety and effectiveness of these devices. FDA recognizes that providing FDA reviewers, 510(k) applicants, and other interested parties information on its review process can promote a consistent and efficient regulatory process.

**II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on premarket notifications (510(k)) for biological indicators intended to monitor sterilizers used in health care facilities. 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 consistent with the GGP regulations.

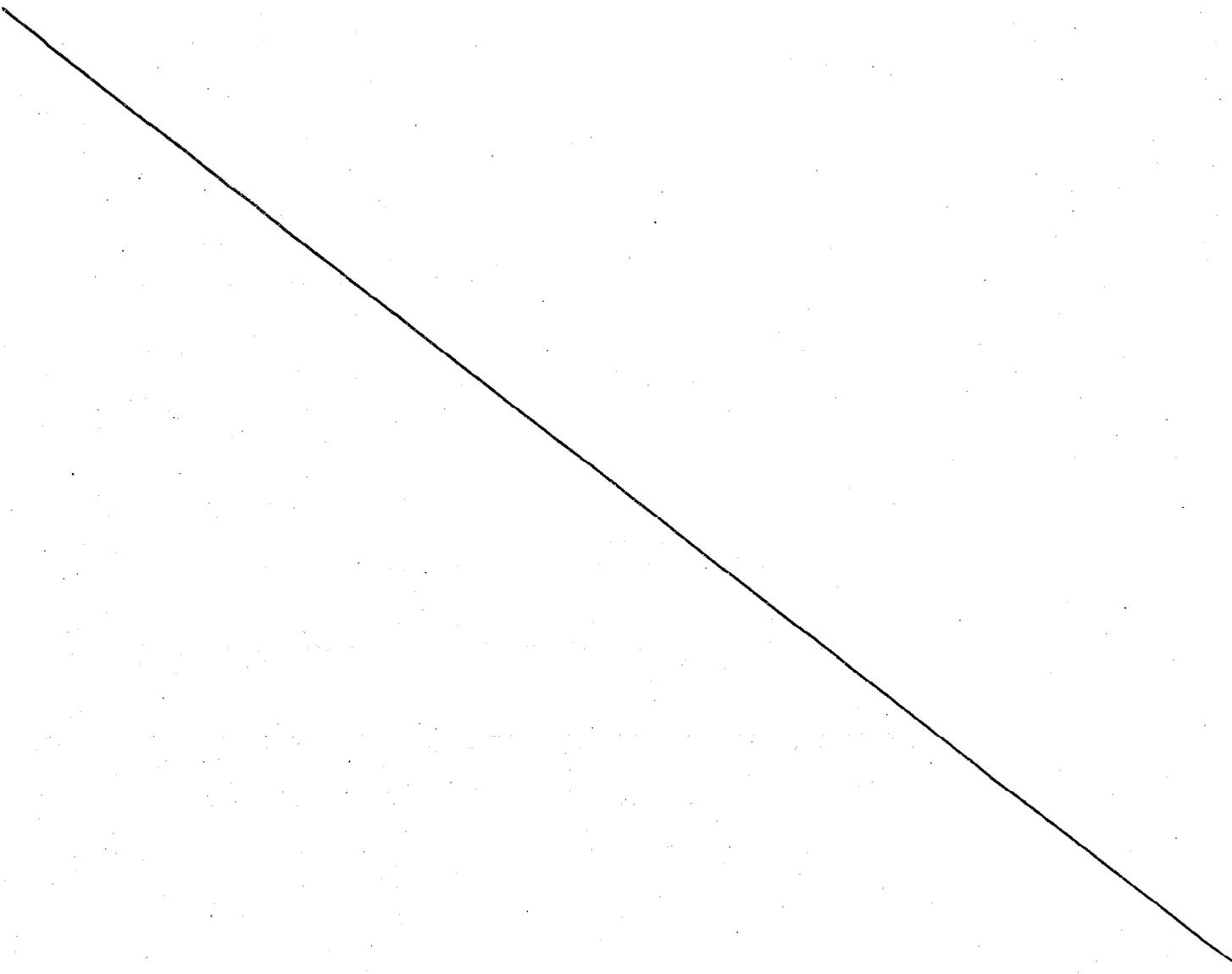
### III. Electronic Access

In order to receive “Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers” 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 (1320) 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>. “Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers” is also available at <http://www.fda.gov/cdrh/ode/guidance/1320.pdf>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

**IV. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by [*insert date 90 days after 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: May 8, 2001  
May 8, 2001.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



Linda S. Kahan

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Center for Devices and Radiological Health.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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