

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0525]

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Certifier N. Hawkins

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Medical Devices; Chemical Indicators Premarket Notification [510(k)]  
Submissions; Draft Guidance for Industry and FDA; Availability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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA." The document is intended to provide guidance for industry and other interested parties for the submission of chemical indicators such as process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this 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on a 3.5" diskette of the guidance document entitled "Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301-443-8818.

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Submit written comments concerning this guidance 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>.

See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**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, extension 143.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This document is intended for applicants who plan to market chemical indicators for health care facilities. It includes guidance on the submission of premarket notification [510(k)] submissions for process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test. Chemical indicators are an integral part of monitoring sterilization processes in health care facilities because they provide the user with information on the effectiveness of a sterilization process. FDA is issuing this draft guidance because the agency recognizes the importance of providing applicants and other interested parties with specific recommendations for the submission of premarket notifications for chemical indicators.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on chemical indicators. 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 requirements of the applicable statute and regulations.

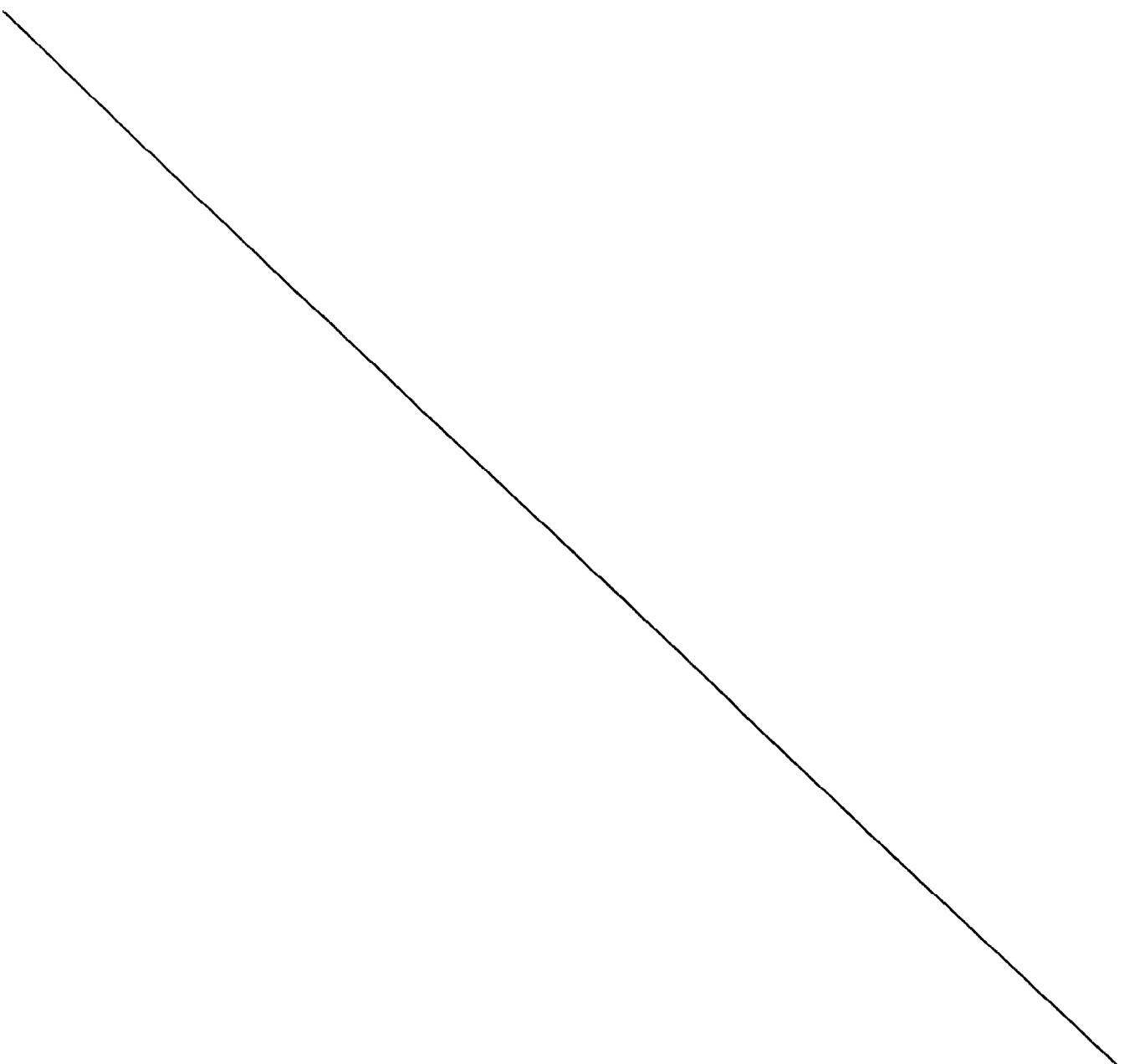
### III. Electronic Access

In order to receive the document “Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA” by fax, 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 (1420) 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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing, and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

#### **IV. Comments**

Interested persons may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Identify comments with the docket number found in



brackets in the heading of this document. The draft guidance document and any comments FDA receives may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/9/03  
January 9, 2003.

Linda A. Kahan

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

[FR Doc. 02-<sup>3</sup>????? Filed ??-??-02<sup>3</sup>; 8:45 am]

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Dawn P. Hawkins