

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0137]

DMB

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Certifier N. Hawkins

**Medical Devices: Draft Guidance for Industry and FDA; Surgical Masks—  
Premarket Notification Submissions; 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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled “Surgical Masks—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and FDA.” This draft guidance is intended to assist industry in preparing premarket notification submissions for surgical masks. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the draft guidance entitled “Surgical Masks—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and FDA” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health,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 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 See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. Identify comments with the docket number found in brackets in the heading of this 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FDA previously issued on its Web site a draft guidance entitled "Draft Guidance for Industry and FDA Reviewers on the Content and Format of Premarket Notification (510(k)) Submissions for Surgical Mask" on January 16, 1998; however, no notice of availability was published in the **Federal Register**. We are seeking to correct that error by issuing the draft guidance again for comment with a notice of availability in the **Federal Register**. FDA will consider the comments received and make every effort to issue the draft guidance for implementation in a reasonable time after the comment period has closed.

We have also revised the draft guidance by adding information concerning industry's option to submit an abbreviated 510(k) and retitled the guidance for clarity.

**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, when finalized, will

represent the agency's current thinking on surgical masks. 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. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the draft guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

### **IV. Comments**

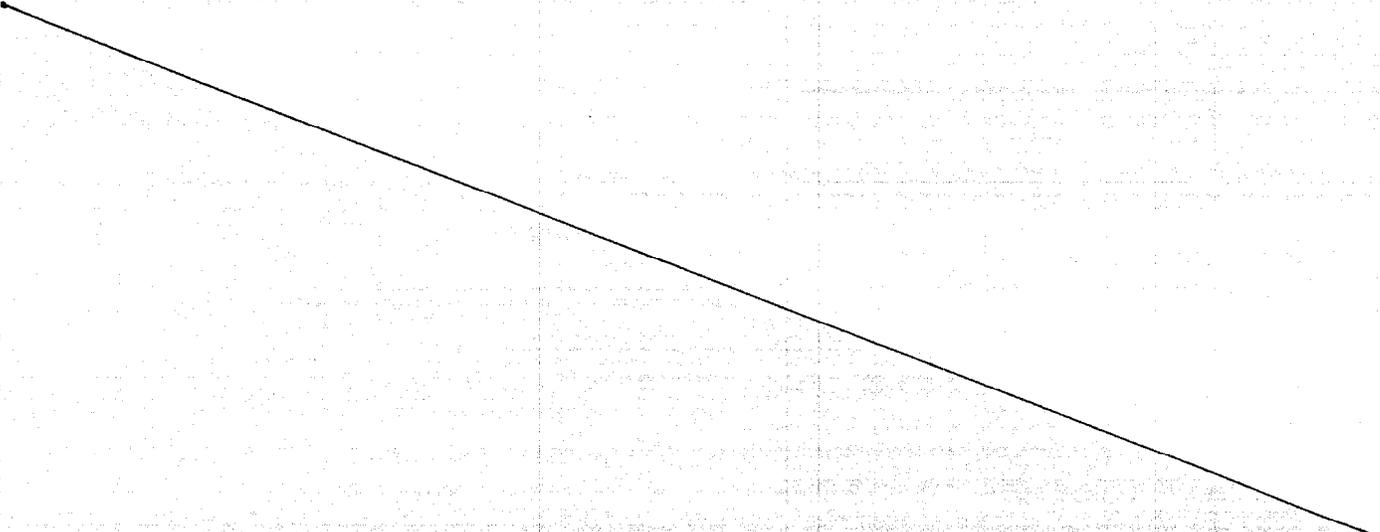
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## V. Electronic Access

The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

To receive a copy of "Surgical Masks—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 (094) 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 by using the Internet. CDRH maintains a site 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.

Dated: 5/5/03  
May 5, 2003.

*Linda S. Kahan*

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

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*Dawn P. Hawkins*