

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Respondents	Total Annual Responses	No. of Responses	Hours per Response	Total Hours
Totals					4,628

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Total Annual Records	No. of Records	Hours per Record	Total Hours
822.31	23	1	23	20	460
822.32	69	1	69	10	690
Totals					1,150

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates, based on current staffing and resources, only one actual PS action and manufacturers' aversion to the stigma of PS over the past year. One PS action will be issued for generic devices comprising of approximately five manufacturers. Each manufacturer will be required to submit a PS plan (§§ 822.9 and 822.10) and interim and final reports on the progress of the surveillance (§ 822.38). FDA anticipates that, on a case-by-case basis, requests for additional information may be made from a manufacturer. FDA expects that a small number of respondents will propose changes to their PS plans (§ 822.21), request a waiver of a specific requirement of this regulation (§ 822.29), or request exemption from the requirement to conduct PS of their device (§ 822.30). FDA's experience has shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes (§ 822.34).

Section 822.25 does not constitute information collections subject to review under the PRA because “* * * they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument * * *” (5 CFR 1320.3(h)(1)).

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 of the act under the Safe Medical

Devices Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 23 manufacturers (6 added each year) and 69 investigators (3 years per surveillance plan). After 3 years, FDA would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued.

Dated: May 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0137]

Medical Devices: Draft Guidance for Industry and FDA; Surgical Masks—Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 June 16, 2003.

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**