TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—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 BURDEN[1]

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.

[FR Doc. 03–12192 Filed 5–14–03; 8:45 am]

BILLING CODE 4160–01–S

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**

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: May 5, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–12193 Filed 5–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps (NHSC) Professional Training and Information Questionnaire (PTIQ) (OMB No. 0915–0208)—Revision

The National Health Service Corps (NHSC) of the HRSA's Bureau of Health Professions (BHPr), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The National Health Service Corps (authorized by the Public Health Services Act, section 331) collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

The PTIQ is used to collect data related to professional issues from NHSC-obligated Scholarship Program Recipients including physicians, physician assistants (PAs), nurse practioners (NPs), certified nurse midwives (CNMs), and other disciplines in the current year's placement cycle. This data is used to match an individual health care professional with the most appropriate clinical practice setting.

The PTIQ will be mailed twelve months in advance of the intended service availability date. Estimates of annualized reporting burden are as follows: