TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section of the 2007 Amendments	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
222[2]	33,490	1	29,900	0.25	7,475
223[2]	16,524	4	66,096	0.5	33,048
Total Hours					40,523

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden.

The estimates in Table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishment owner/operators, for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a device establishment's owner/operator is required to register and list, they would need only to have access to a computer, Internet and an e-mail address for registration and listing by electronic means, the agency did not anticipate receipt of a large number of requests for waiver. For the first few months of operation of the web-based system, from the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded.

Based on information taken from our databases, FDA estimates that there are 29,370 owner/operators who collectively register a total of 33,490 device establishments. The number of respondents listed for section 224 of FDAAA in Table 1 of this document is 29,370, which corresponds to the number of owner/operators who annually register one or more establishments. In addition, FDA estimates that 4,988 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in Table 1 of this document for section 223 of FDAAA is 24,382, which corresponds to the number of owner/operators who annually list one or more devices (29,370 – 4,988 = 24,382).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than one tenth of 1 percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than 1 percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 21 waiver requests, which could increase by only one additional request each year.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in Table 2 of this document, complies with the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only upon request from FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for recordkeeping requirements under section 223 of FDAAA in Table 2 of this document reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29459 Filed 12–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0611]

Draft Guidance for Industry and Food and Drug Administration Staff; Submission and Review of Sterility Information in Premarket Notification Submissions for Devices Labeled as Sterile; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.'' This draft guidance document updates and clarifies the procedures for reviewing premarket notification submissions (510(k)s) for devices labeled as sterile, particularly with respect to sterilization technologies FDA considers novel, and the information that should be included in 510(k)s for devices labeled as sterile.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 12, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile'' to the Division of Small Manufacturers, International, and

Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240–276–3151. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Steven Turtil, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3747;

Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700; or

Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document updates and clarifies the procedures for reviewing premarket notification submissions (510(k)s) for devices labeled as sterile, particularly with respect to sterilization technologies FDA considers novel. The draft guidance provides details about the pyrogenicity information we recommend be included in 510(k)s for devices labeled as sterile. When final, this draft will supersede the guidance entitled ''Updated 510(k) Sterility Review Guidance K90–1'' that FDA issued on August 30, 2002 (available at *http://www.fda.gov/cdrh/ode/guidance/361.pdf*).

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 premarket notification submissions for devices labeled as sterile. 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

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1615 to identify the guidance you are requesting.

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 CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or the Division of Dockets Management Internet site at *http://www.regulations.gov*.

IV. 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). This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29413 Filed 12–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 3, 2008, page 57634, and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it