Dated: December 2, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0499]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 12, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submissions@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0625. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), (including the submission of updated information), be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. FDA expects 20,000 to 30,000 device establishments to begin registering electronically at that time.

Section 222 of FDAAA amends section 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

In the **Federal Register** of October 1, 2008 (73 FR 57106), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the 2007 Amend-ments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
222[2]	3673	2,600	1	2,704	0.5	1,352
223[2]	3673	24,382	1	24,382	0.25	6,095
224[2]		29,370	1	29,370	0.75	22,028
224[3]		2,600	1	2,600	0.5	1,300
224 (waiver request)[2]		20	1	20	1	20
224 (waiver request)[3]		1	1	1	1	1
Total Hours						30,796

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual increase in burden.

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]

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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