

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Hinkins

[Docket No. FDA-2008-N-0088] (formerly Docket No. 2008N-0016)

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Additional Listing Information for Medical Device Registration and Listing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**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 *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0387. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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**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.

**Additional Listing Information for Medical Device Registration and Listing—(OMB Control Number 0910–0387)—Extension**

The Food and Drug Administration Amendments Act of 2007 (the 2007 Amendments), enacted September 27, 2007, requires that device establishment registrations and listings under 21 U.S.C. 360(p) (including the submission of updated information), be submitted to the Secretary of Health and Human Services (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. See section 224 of the 2007 Amendments. The 2007 Amendments provides for an October 1, 2007, effective date. FDA expects 20,000 to 30,000 establishments will need to register between now and December 31, 2008. FDA is seeking OMB approval for the information collected by electronic means. Registration by electronic means for device establishments will mean replacement of FDA Forms 2891 and 2891a, “Registration of Device Establishment” and FDA Form 2892 “Medical Device Listing,” with electronic versions. However, for OMB approval of the extension request for this collection of information, FDA is revising the scope to address only the reporting and recordkeeping requirements by non-electronic means as described in this document and set forth in § 807.31 (21 CFR 807.31) for “Additional Listing Information.” To reflect the revised scope of this collection of information, FDA has modified the title.

Under § 807.31(a) through (d), each owner or operator is required to maintain an historical file containing the labeling and advertisements in use

on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements, under § 807.31(e), the owner or operator must be prepared to submit to FDA copies of: (1) All device labeling, (2) all device labeling and representative advertising, or (3) only representative package inserts, depending upon whether the device is subject to the regulatory controls under section 514 or section 515 of Federal Food, Drug, and Cosmetic Act (the act), or restrictions imposed by 21 CFR 801.109 or otherwise by section 520(e) of the act.

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution in order to effectively allocate FDA's field resources for these inspections, and (3) the class of the device that determines the frequency of inspection. As a result, when complications occur with a particular device or component, all manufacturers of similar or related devices can easily be identified.

The likely respondents to this information collection are domestic and foreign device establishments who must register and submit a device list to FDA, e.g., establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

In the **Federal Register** of February 5, 2008 (73 FR 6731), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 807.31(e)      | 200                | 1                             | 200                    | .50                | 100         |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section      | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---------------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 807.31(a through d) | 16,200               | 4                                  | 64,800               | .50              | 32,400      |

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

The annual respondent reporting burden for device establishment registrations and listing is estimated to be 100 hours and the annual respondent recordkeeping burden is estimated to be 32,400 hours. The estimates cited in tables 1 and 2 of this document are based primarily on the annual FDA accomplishment report, which includes actual FDA registration and listing data derived for fiscal year (FY) 2006. These estimates are also based on FDA estimates of FY 2006 data from current systems and conversations with industry and trade association representatives. FDA anticipates reviewing annually, 200 historical files.

Dated: 4/23/08  
April 23, 2008.



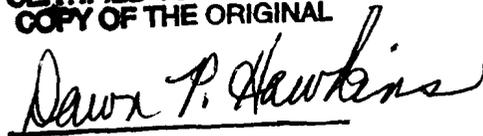
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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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