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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2008N-0016]

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Certifier A. Corbin

Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Listing Information for Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits public comments on the reporting and recordkeeping burden associated with the paperwork requirements under § 807.31 (21 CFR 807.31), which requires device establishments to retain and, upon FDA's specific request, submit certain additional listing information.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug

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Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

**Additional Listing Information for Medical Device Registration and Listing—
21 CFR 80.31; (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 by which FDA expects approximately 30,000 establishments to begin registering. 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 under § 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 Sections 514 or 515 of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d and 360e, respectively), 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

¹There 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	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
807.31(a) through (d)	16,200	4	64,800	.50	32,400

¹There 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

Dated: JAN 30 2008
January 30, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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