hours. These figures have been rounded up. The burden estimates cited in tables 1 and 2 of this document are based primarily upon the data and methods provided in FDA's assessment for fiscal year (FY) 1999 entitled ''A Cost Assessment of Medical Device Tracking.'' Using implantation procedures from the National Center for Health Statistics, FDA applied a 2-percent annual growth rate to estimate the number of procedures for tracked implant devices for FY1997 through FY2006. This assessment also used unit shipment data in combination with various growth rates to estimate annual sales distribution for the tracked l/s-l/s devices over the same time period. In addition, the assessment also estimated the burden on industry for developing and maintaining tracking systems for these medical devices for FY1997 through FY2006.

For the annual recordkeeping burden, the number of respondent medical device manufacturers subject to device tracking is estimated to be 229 and is based on data from FDA's manufacturers database. FDA issued tracking orders to 20 additional medical device manufacturers during the time period for FY2002 through FY2004. Under § 821.25(c), the additional medical device manufacturers collectively bear a one-time recordkeeping burden of 10,560 hours to develop a medical device tracking system. FDA's estimate of 17,000 medical device distributor respondents contained in this assessment, are derived from Dun & Bradstreet sources on medical equipment wholesalers, retailers, home care dealers, and rental companies. Health Forum, an American Hospital Association Company, provided statistics on hospitals.

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 FDMS only.

Dated: January 30, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2078 Filed 2–4–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2008N–0016]

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 April 7, 2008.

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 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 BURDEN[1]

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

[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	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

[1]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 documet 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: January 30, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review: Comment Request Questionnaire Cognitive Interview and Pretesting (ARP/DCCPS/NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 26, 2007 (Vol. 72, No. 226, p. 65969) and allowed 60 days for public comment. No public comments were 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 displays a currently valid OMB control number.

Proposed Collection: Title: Questionnaire Cognitive Interview and Pretesting. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the data collection is to conduct cognitive interviews, focus groups, Pilot household interviews, and experimental research in laboratory and field settings, both for applied questionnaire evaluation and more basic research on response errors in surveys. The most common evaluation method is the cognitive interview, in which a questionnaire design specialist interviews a volunteer participant. The interviewer administers the draft survey questions as written, but also probes the participant in depth about interpretations of questions, recall processes used to answer them, and adequacy of response categories to express answers, while noting points of confusion and errors in responding. Interviews are generally conducted in small rounds of 10–15 interviews. When possible, cognitive interviews are conducted in the survey's intended