currently in the HDS. FDA believes that adding the pet food labeling questions to the HDS is the most cost effective way of collecting this information and precludes the need for a separate pet food labeling survey, thus reducing the overall burden to the public.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Statutory Authority	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Public Law 110–85 Sec. 1002(a)(3)	1,000	1	1,000	0.08	80

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

This burden estimate does not represent a new estimate of burden hours. Instead, it represents the estimated number of respondents and burden hours that will be used from the current approval for 0910–0545 to conduct the pet food labeling questions. The total estimated burden for 0910–0545 is 1,300 hours. 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: April 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9373 Filed 4–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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.

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 May 30, 2008.

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.

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[1]

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

[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 per 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 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: April 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9374 Filed 4–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0222] (formerly Docket No. 2008N–0007)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

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 May 30, 2008.

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 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)—(OMB Control Number 0910–0167)—Extension

Sections 525 and 526 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa and 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable