monkeys, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals is necessary for CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and to determine whether the measures being taken are adequate to prevent exposure of persons and animals during importation. CDC will monitor at least 2 shipments to be assured that the provisions of a special permit plan are being followed by a new permit holder. CDC will assure that adequate disease control practices are being used by new permit holders before the special permit is extended to cover the receipt of additional shipments under the same plan for a period of 180 days, and may be renewed upon request. This extension eliminates the burden on importers to repeatedly report identical information, requiring submission only of specific shipment itineraries and information on changes to the plan which require approval.

Respondents are businesses or not-for-profit organizations that import nonhuman primates. The burden represents full disclosure of information and itinerary/change information, respectively. There are no costs to respondents except for their time to complete the requisition process.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Instrument	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden
Request for Special Permit	Businesses (limited permit)	5	2	30/60	5
Request for Special Permit	Businesses (extended permit)	1	3	10/60	0.5
Request for Special Permit	Organizations (limited permit)	3	2	30/60	3
Request for Special Permit	Organizations (extended permit)	12	2	10/60	4
Total					12.5

Dated: November 30, 2010.

Carol Walker,

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

[FR Doc. 2010–30618 Filed 12–6–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0606]

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 comments on the reporting and recordkeeping burden requirements associated with additional listing information for medical device registration and listing by non-electronic means.

DATES: Submit either electronic or written comments on the collection of information by February 7, 2011.

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: Daniel Gittleson, Office of Information Management Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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 (OMB Control Number 0910–0387)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA), 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. The collections of information under sections 222, 223, and 224 of FDAAA have been approved under OMB control number 0910–0625. Registration by electronic means for device establishments replaced FDA Forms 2891 and 2891a, "Registration of Device Establishment," and FDA Form 2892, "Medical Device Listing," with FDA Form 3673, "Device Registration and Listing Module." The scope of this information collection addresses only the reporting and recordkeeping requirements by non-electronic means under § 807.31 (21 CFR 807.31).

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 not 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. Section 807.31(e) requires that the owner or operator 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 and 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d and 360e), or restrictions imposed by 21 CFR 801.109 or otherwise by section 520(e) of the FD&C Act.

The information collected under these provisions is used by FDA to identify: (1) Firms subject to FDA's regulations, (2) geographic distribution of firms in order to effectively allocate FDA's field resources for 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	Number of respondents	Annual frequency of response	Total annual responses	Hours per response	Total hours
807.31(d)(2)	2,250	1	2,250	.5	1,125
807.31(e)	22,500	1	22,500	.5	11,250
Total					12,375

[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	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
807.31(a–c)	22,500	4	90,000	0.50	45,000
Total					45,000

[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 listings for additional information is estimated to be 12,375 hours and the annual respondent recordkeeping burden is estimated to be 45,000 hours. Therefore, the total burden hours for this collection are estimated to be 57,375. The estimates cited in tables 1 and 2 of this document are based primarily on fiscal year 2010 data from current systems and on conversations with industry and trade association representatives.

Dated: December 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30582 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0088]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Products—General Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Electronic Products—General Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@FDA.HHS.GOV.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 2010 (75 FR 26964), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned