TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Technical and safety information for users—1002.3	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41	50	3	150	1	150
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems—1020.30(g)	100	2	200	55	11,000
Statement of maximum line current of x-ray systems—1020.30(g)(2)	15	1	15	10	150
Diagnostic x-ray system safety and technical information—1020.30(h)(1)–(h)(4)	100	2	200	200	40,000
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)–(h)(6) and 1020.32(a)(1), (g), and (j)(4)	15	2	30	25	750
CT equipment—1020.33(c)–(d), (g)(4), and (j)	25	2	50	150	7,500
Cabinet x-ray systems information—1020.40(c)(9)(i)–(c)(9)(ii)	30	2	60	40	2,400
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i)–(c)(5)(iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i)–(h)(1)(vi)	1,000	1.2	1,200	20	24,000
Laser product service information—1040.10(h)(2)(i)–(h)(2)(ii)	1,000	1.2	1,200	20	24,000
Medical laser product instructions—1040.11(a)(2)	35	1	35	10	350
Sunlamp products instructions—1040.20	10	5	50	10	500
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	2	1	2	1	2
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	2	1	2	1	2
Ultrasonic therapy products—1050.10(d)(1)–(d)(4), (f)(1), and (f)(2)(iii)	5	1	5	56	280
Total					111,139

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

The following requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c), 1003.10(a) through (c), 1003.11(a)(3) and (b), 1003.20(a) through (h), 1003.21(a) through (d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a) through (i), 1004.3(a) through (i), 1004.4(a) through (h), 1005.21(a) through (c), and 1005.22(b). These requirements apply to the collection of information during the conduct of investigations or audits (5 CFR 1320.4).

The following labeling requirements are not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1030.10(c)(6); 1040.10(g); 1040.20(d)(1)(i), (d)(2)(i), and (d)(2)(iii); and 1040.30(c)(1).

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25962 Filed 10–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Medical Devices: The Pre-Submission Program and Meetings With FDA Staff

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 December 2, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—NEW and Title: ''Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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.

Guidance on Medical Devices: Pre-Submission Program and Meetings With FDA Staff—(OMB Control Number 0910—NEW)

This guidance describes the Pre-Submission program for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission Package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. In addition to Pre-Submissions, the guidance addresses other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings and the procedures to request feedback using these mechanisms. When approved by OMB, this guidance document will supersede ''Pre-IDE Program: Issues and Answers—Blue Book Memo D99–1'' dated March 25, 1999.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission Packages in order to implement this voluntary submission program.

Over time, the FDA pre-investigational device exemption (pre-IDE) program evolved to include feedback on premarket approval (PMA) applications, humanitarian device exemption applications, Evaluation of Automatic Class III Designations (de novo petitions), 510(k) submissions, Clinical Laboratory Improvement Amendments categorization requests, as well as to address questions related to whether a clinical study requires submission of an IDE. During discussions with representatives of the medical device industry in the development of the Agency's recommendations for the Medical Device User Fee Amendments of 2012 (MDUFA III) (Pub. L. 112–144), both the industry and the Agency agreed that the Pre-Submission (formerly pre-IDE) process provided important additional transparency to the IDE and premarket review processes. In response, the Secretary's 2012 Commitment Letter to Congress (MDUFA III Commitment Letter) included FDA's commitment to institute a structured process for managing Pre-Submissions.

To fulfill the Secretary's commitment to the industry, this final guidance: (1) Describes the Pre-Submission program (formerly the IDE program) for medical devices reviewed in CDRH and CBER; (2) describes other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings; (3) assists device manufacturers and their representatives who seek meetings with the FDA by providing guidance and recommendations regarding information that should be included in a Pre-Submission Package or other request for feedback; and (4) provides guidance as to the procedures that CDRH and CBER intend to follow when industry representatives or application sponsors request a meeting with review staff.

In the **Federal Register** of July 13, 2012 (77 FR 41413), FDA published a notice of availability combined with a 60-day notice requesting public comment on the proposed collection of information. FDA received no PRA-related comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

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

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA estimates that it will receive approximately 2,544 pre-submission packages annually. The Agency reached this estimate by reviewing the number of submissions received by the Agency under the Pre-IDE program over the past 10 years. Based on FDA's experience with the Pre-IDE program, FDA expects the Pre-Submission program to continue to be utilized as a viable program in the future and expects that the number of pre-submission packages will increase over its current rate and reach a steady state of approximately 2,544 submissions per year.

FDA estimates from past experience with the Pre-IDE program that the complete process involved with the program takes approximately 137 hours. This average is based upon estimates by FDA administrative and technical staff that is familiar with the requirements for submission of a Pre-Submission and related materials, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 348,528 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of respondents	Total burden hours annualized	Hourly wage rate	Total cost annualized
2,544	137	$150	$52,279,200

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

The average to industry per hour for this type of work is $150, resulting in a cost of $20,550 per respondent. The estimated submission cost of $20,550 multiplied by 2,544 submissions per year equals $52,279,200, which is the aggregated industry reporting cost annualized.

FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current pre-submissions, estimate that an average of 137 hours is required to prepare a pre-submission. However, we recognize there is a variance in the preparation submission because of the vast and varying complexities of medical devices.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25964 Filed 10–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

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 December 2, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567—(0910–0338)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved Biologics Licensing Application (BLA) must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the