TABLE 2—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
601.6(a)	1	20	20	*0.33	6.6

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

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25961 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–0663]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

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 0910–0672. 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.

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans—(OMB Control Number 0910–0672)—Extension

In the **Federal Register** of September 29, 2010 (75 FR 59935), FDA published a document entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' The document clarified the Agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implemented internationally harmonized definitions and reporting standards for IND safety reports. The document also required safety reporting for bioavailability and bioequivalence studies. The document was intended to improve the utility of IND safety reports, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, and harmonize safety reporting requirements internationally.

The rulemaking included the following information collection under the PRA that was not already included in 21 CFR 312.32 and approved under OMB control number 0910–0014.

Section 312.32(c)(1)(ii) and (c)(1)(iii) requires reporting to FDA, in an IND safety report, of potential serious risks from clinical trials within 15 calendar days for findings from epidemiological studies, pooled analyses of multiple studies, or other clinical studies that suggest a significant risk in humans exposed to the drug.

Section 312.32(c)(1)(iii) specifies the requirements for reporting to FDA in an IND safety report potential serious risks from clinical trials within 15 calendar days for findings from in vitro testing that suggest a significant risk to humans. FDA estimates that approximately 100 sponsors spend a total of approximately 12 hours per report to prepare and submit approximately 600 reports annually.

Section 312.32(c)(1)(iv) requires reporting to FDA in an IND safety report within 15 calendar days of any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or investigator brochure. FDA estimates that approximately 10 sponsors spend a total of approximately 12 hours per report to prepare and submit approximately 10 reports annually.

The rulemaking also included new information collection under the PRA by requiring safety reporting for bioavailability and bioequivalence studies (21 CFR 320.31(d)). FDA estimates that approximately 10 sponsors spend a total of approximately 14 hours per report to prepare and submit approximately 200 reports annually.

In the **Federal Register** of June 12, 2013 (78 FR 35283), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	10	20	200	14	2,800
312.32(c)(1)(ii) and (c)(1)(iii)—IND Safety Reports [2]	100	6	600	12	7,200
312.32(c)(1)(iv)—IND Safety Reports [3]	10	1	10	12	120
Total					10,120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information. The estimates are for the additional burdens beyond those already approved for current §§ 312.32 and 312.64.

[2] Includes reports based on findings suggesting a significant risk in humans from epidemiological studies, pooled analysis of multiple studies, other clinical studies, or in vitro testing. Reports from animal testing are not included.

[3] Includes reports of clinically important increases in the rate of occurrence of serious, expected suspected adverse reactions.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25959 Filed 10–30–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0825]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

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 0910–0231. 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.

Premarket Approval of Medical Devices—(OMB Control Number 0910–0231)—Extension

Under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e) all devices placed into class III by FDA are subject to premarket approval requirements. Premarket approval (PMA) is the process of scientific and regulatory review to ensure the safety and effectiveness of class III devices. An approved PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and cannot be marketed. Premarket approval requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices.

Manufacturers of class III preamendments devices, devices that were in commercial distribution before May 28, 1976, are not required to submit a PMA until 30 months after the issuance of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after issuance of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices determined by FDA to be substantially equivalent to preamendments class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into class I or II are ''new'' devices and fall automatically into class III. Before such devices can be marketed, they must have an approved premarket approval application or be must reclassified into class I or class II.

The Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) was enacted on November 21, 1997, to implement revisions to the FD&C Act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. FDAMA added section 515(d)(6) to the FD&C Act, which provided that PMA supplements were required for all device changes that affect safety and effectiveness unless such changes are modifications to manufacturing procedures or method of manufacture. That type of manufacturing change will require a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulations' purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for class III medical devices. The regulations facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the denial of PMAs and supplements to PMAs for devices that have not been