

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2013-N-0663]

Agency Information Collection Activities; Proposed Collection; 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 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 information collection resulting from investigational new drug (IND) safety reporting requirements and safety reporting requirements for bioavailability and bioequivalence studies.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-7726, ila.mizrachi@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.

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.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

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	100	6	600	12	7,200
312.32(c)(1)(iv) IND Safety Reports	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.

Dated: June 7, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-M-0036, FDA-2013-M-0205, FDA-2013-M-0255, FDA-2013-M-0281, FDA-2013-M-0282, and FDA-2013-M-0343]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the

Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will

continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2013, through March 31, 2013. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2013, THROUGH MARCH 31, 2013

PMA No., docket No.	Applicant	Trade name	Approval date
P110014, FDA-2013-M-0036	Dune Medical Devices, Inc	MarginProbe System	December 27, 2012.
H110002, FDA-2013-M-0205	Second Sight Medical Products, Inc	Argus™ II Retinal Prosthesis System	February 13, 2013.
P110032, FDA-2013-M-0282	Lombard Medical	Aorfix AAA Flexible Stent Graft System	February 14, 2013.
P040046, FDA-2013-M-0255	Allergan	Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.	February 20, 2013.
P110013/S005, FDA-2013-M-0343	Medtronic Vascular, Inc	Resolute Integrity Zotarolimus-Eluting Coronary Stent System.	February 22, 2013.
P100030, FDA-2013-M-0281	Tenaxis Medical, Inc	ArterX Surgical Sealant	March 1, 2013.

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/>

DeviceApprovalsandClearances/PMAApprovals/default.htm.

Dated: June 7, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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