Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0477]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records

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 investigational device exemptions reports and records.

DATES: Submit either electronic or written comments on the collection of information by July 23, 2012.

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.

Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910–0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) added section 520(g)(6) to the FD&C Act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the FD&C Act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, i.e., devices that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements. The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available. Section 812.10 permits the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety. Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations.

Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in the original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE.

Upon approval of an IDE application by FDA, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation that affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Section 812.150 requires a sponsor to submit reports to FDA.

These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress. Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this information to determine if wider distribution of the device is in the interest of the public health. Section 812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device and to ensure the integrity of the controlled clinical trials.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waivers/812.10	1	1	1	1	1
IDE application/812.20, 812.25, and 812.27	356	1	356	80	28,480
Supplements/812.35 and 812.150	356	12	4,272	6	25,632
Treatment IDE applications/812.36(c)	1	1	1	120	120
Treatment IDE reporting/812.36(f)	1	1	1	20	20
Total					54,253

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

Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study, records of receipt, use or disposition of devices, records of each subject's case history and exposure to the device, informed consent documentation, study protocol, and documentation of any deviation from the protocol. Sponsors are required to maintain records including correspondence and reports concerning the study, records of shipment and disposition, signed investigator agreements, adverse device effects information, and, for a nonsignificant risk device study, an explanation of the nonsignificant risk determination, records of device name and intended use, study objectives, investigator information, investigational review board information, and statement on the extent that good manufacturing practices will be followed.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original/812.140	356	1	356	10	3,560
Supplemental/812.140	356	12	4,272	1	4,272
Nonsignificant/812.140	356	1	356	6	2,136
Totals					9,968

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

For a nonsignificant risk device investigation, the investigator's and sponsor's recordkeeping and reporting burden is reduced. Pertinent records on the study must be maintained by both parties, and reports are made to sponsors and institutional review boards (IRBs). Reports are made to FDA only in certain circumstances, e.g., recall of the device, the occurrence of unanticipated adverse effects, and as a consequence of certain IRB actions.

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
Reports for Nonsignificant Risk Studies/812.150	1	1	1	6	6

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

The estimate of the burden is based on the number of IDEs received in the last 3 years.

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0915]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

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 June 25, 2012.

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 0910–0636. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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 for Industry on Postmarketing Adverse Event Reporting for Nonprescription

Human Drug Products Marketed Without an Approved Application (OMB Control Number 0910–0636)—Extension.

Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)) appears on the label of a nonprescription drug marketed in the United States.

FDA is requesting public comment on estimates of annual submissions from these respondents, as required by Public Law 109–462 and described in the guidance. This guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including follow-up reports under 760(c)(2) of the FD&C Act, and how to submit these reports. The estimates for annual reporting burden and recordkeeping are based on FDA's knowledge of adverse drug experience reports historically submitted per year for prescription drug products and for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports and to maintain records.

FDA receives approximately 2,500 serious adverse event reports for nonprescription drug products marketed under approved applications, which comprise approximately 20 percent of the overall nonprescription drug market. Based on this experience, we estimate between 10,000 and 15,000 (i.e., 12,500) total annual responses for nonprescription drugs marketed without an approved application.

In the **Federal Register** of December 27, 2011 (76 FR 80946), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments on the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reports of serious adverse drug events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	2	25,000
Total					25,000

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

Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance recommends that responsible persons maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports. Although the guidance does not provide recommendations on recordkeeping activities generally under section 760(e) of the FD&C Act, FDA is providing an estimate for the burden of this collection. Historically, serious adverse event reports comprise approximately two-thirds and nonserious adverse event reports comprise approximately one-third of the total number of postmarketing adverse event reports associated with drugs and biologic therapeutics (except vaccines) received by FDA. Based on this generalization, FDA estimates the total annual records to be approximately 20,000 records per year. FDA estimates that it takes 5 hours to maintain each record and the recordkeeping burden as follows: