Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information OMB Control Number 0910–0754—Extension

This final Guidance for Industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information'' offers specific guidance to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising.

This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

Based on a review of FDA's Document Archiving, Reporting, and Regulatory Tracking System for 2012–2015, we identified DHCP letters that were sent and the identity of each sponsor sending out a DHCP letter for each year. We estimate that we will receive approximately 25 DHCP Letters annually from approximately 18 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Average	18	1.4	25	100 hours	2,500

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

Dated: March 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05301 Filed 3–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0477]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 April 11, 2016.

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 0910–0078. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Device Exemptions Reports and Records— 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.

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.

For a nonsignificant risk device investigation, the investigators' and sponsors' 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. The estimate of the burden is based on the number of IDEs received in recent years.

In the **Federal Register** of October 28, 2015 (80 FR 66009), 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 [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	219	1	219	80	17,520
Supplements—812.35 and 812.150	579	6	3,474	6	20,844
Treatment IDE Applications—812.36(c)	1	1	1	120	120
Treatment IDE Reporting—812.36(f)	1	1	1	20	20
Total					38,505

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

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	219	1	219	10	2,190
Supplemental—812.140	579	6	3,747	1	3,474
Nonsignificant—812.140	356	1	356	6	2,136
Total					7,800

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

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 estimated annual reporting burden for this extension has decreased to 38,505 hours (previously 54,253 hours) as the result of a decrease in the average number of applications and supplements submitted. For the same reason, the recordkeeping burden has decreased to 7,800 hours (previously 9,968). The previous approved total burden hours of 64,227, have therefore decreased by 17,916 to 46,311.

Dated: March 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05385 Filed 3–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0986]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2016 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to request to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit either an electronic or written request for participation in the ELP by April 11, 2016.

ADDRESSES: Submit either electronic requests to *http://www.regulations.gov* or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify requests with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5261, Silver Spring, MD 20993–0002, 240–402–2246, FAX: 301–827–3079, *Christian.Hussong@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for helping to ensure the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711).

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States