the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 21, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 22, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21834 Filed 10–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3500]

Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Tuesday, August 20, 2019. The document announced a ''Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1.'' The document was published with the incorrect contact name, phone number, and email address in the **FOR FURTHER INFORMATION CONTACT** section. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jesse Anderson, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–348–1816, *Jesse.Anderson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2019–17877, appearing on page 43139, in the **Federal Register** of Tuesday, August 20, 2019 (84 FR 43139), the following correction is made:

On page 43140, in the first column, in the **FOR FURTHER INFORMATION CONTACT** section of the document, ''Isaac Chang, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–4027501, PRAStaff@fda.hhs.gov.'' is corrected to read ''Jesse Anderson, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–348–1816, *Jesse.Anderson@fda.hhs.gov.*''

Dated: September 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21784 Filed 10–4–19; 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 November 6, 2019.

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10a.m.–12p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 (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 of any of the requirements of part 812. Sections 812.20, 812.25, and 812.27 describe 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.

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.

In the **Federal Register** of June 11, 2019 (84 FR 27139), 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	229	1	229	80	18,320
Supplements—812.35 and 812.150	654	5	3,270	6	19,620
Treatment IDE Applications—812.36(c)	1	1	1	120	120
Treatment IDE Reporting—812.36(f)	1	1	1	20	20
Total					38,081

[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	229	1	229	10	2,290
Supplemental—812.140	654	5	3,270	1	3,270
Nonsignificant—812.140	356	1	356	6	2,136
Total					7,696

[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.

Our estimated burden for the information collection reflects an overall decrease of 528 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: September 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21785 Filed 10–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Interdisciplinary, Community Based Linkages

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Interdisciplinary, Community Based Linkages (ACICBL) will hold public meetings for the 2020 calendar year (CY). Information about ACICBL, agendas, and materials for these meetings can be found on the ACICBL website at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html.*

DATES: February 20–21, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; May 1, 2020, 10:00 a.m.–4:00 p.m. ET; October 20, 2020, 10:00 a.m.–4:00 p.m. ET.

ADDRESSES: The meeting scheduled from February 20–21, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857 and can be accessed via teleconference and Adobe Connect webinar. The meetings scheduled on May 1, 2020, and October 20, 2020, will both be held via teleconference and Adobe Connect webinar. Instructions for joining the meetings either in-person or remotely will be posted on the ACICBL website 30 business days before the date of the meeting. For meeting information updates, go to the ACICBL website meeting page at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Joan Weiss, Ph.D., RN, CRNP, FAAN, Senior Advisor and Designated Federal Official, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0430; or *BHWACICBL@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACICBL provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning activities under sections 750–760, Title VII, Part D of the Public Health Service Act. Agenda items are subject to change as priorities dictate. ACICBL meetings and agenda items for CY 2020 may include, but are not limited to, discussion and development of topics for the 18th report. Refer to the ACICBL website listed above for all current and updated information concerning each of the CY 2020 ACICBL meetings, including draft agendas and meeting materials that will be posted before each meeting. Agendas will be posted on the ACICBL website at least 14 calendar days before each meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACICBL should be sent to Joan Weiss using the contact information above at least 5 business days before the scheduled meeting date.

Individuals who need special assistance or another reasonable accommodation should notify Joan Weiss using the contact information listed above at least 10 business days before the meeting they wish to attend. Since the in-person meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–21797 Filed 10–4–19; 8:45 am]

BILLING CODE 4165–15–P