methods for demonstrating OINDP therapeutic equivalence.

Registration: Persons interested in attending this public workshop must register online by December 30, 2017, by going to *https://www.fda.gov/Drugs/NewsEvents/ucm576064.htm.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. The workshop agenda and other background materials will be available approximately 2 weeks before the workshop at *https://www.fda.gov/Drugs/NewsEvents/ucm576064.htm.* The agenda will include time for questions and answers throughout the day and for general comments and questions from the audience following panel discussions.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by December 30, 2017, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:30 a.m.

If you need special accommodations due to a disability, please contact Renishkumar Delvadia no later than December 30, 2017.

Streaming Webcast of the public workshop: This public workshop will also be webcast. A live webcast of this workshop will be viewable at *https://collaboration.fda.gov/r19djs3yfsf/* on the day of the workshop. A video record of the workshop will be available at the same web address for 1 year. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: December 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27279 Filed 12–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

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 January 18, 2018.

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 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Good Laboratory Practice Regulations for Nonclinical Studies—21 CFR Part 58

OMB Control Number 0910–0119—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses, and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

Recordkeeping is necessary to document the conduct of nonclinical laboratory studies of FDA-regulated products to ensure the quality and integrity of the resulting final study report on which a regulatory decision may be based. Written SOPs and records of actions taken are essential for testing facilities to implement GLPs effectively. Further, they are essential for FDA to be able to determine a testing facility's compliance with the GLP regulations in part 58.

In a notice of proposed rulemaking published in the **Federal Register** of August 24, 2016 (81 FR 58342), we proposed changes in our GLP regulations, including some of those listed in tables 1 and 2 of this document. The document included

revised burden estimates for the proposed changes and solicited public comment. In response to requests, the comment period was extended to January 21, 2017 (81 FR 75351, October 31, 2016). In the interim, FDA is seeking an extension of OMB approval for the current regulations so that we can continue to collect information while the proposal is pending.

Description of Respondents: The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or government agencies.

In the **Federal Register** of April 25, 2017 (82 FR 19054), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
58.35(b)(7); Quality assurance unit	300	60.25	18,075	1	18,075
58.185; Reporting of nonclinical laboratory study results	300	60.25	18,075	27.65	499,774
Total					517,849

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
58.29(b); Personnel	300	20	6,000	.21 (13 minutes)	1,260
58.35(b)(1)–(6), and (c); Quality assurance unit	300	270.76	81,228	3.36	272,926
58.63(b) and (c); Maintenance and calibration of equipment.	300	60	18,000	.09 (5 minutes)	1,620
58.81(a)–(c); SOPs	300	301.8	90,540	.14 (8 minutes)	12,676
58.90(c) and (g); Animal care	300	62.7	18,810	.13 (8 minutes)	2,445
58.105(a) and (b); Test and control article characterization.	300	5	1,500	11.8	17,700
58.107(d); Test and control article handling	300	1	300	4.25	1,275
58.113(a); Mixtures of articles with carriers	300	15.33	4,599	6.8	31,273
58.120; Protocol	300	15.38	4,614	32.7	150,878
58.195; Retention of records	300	251.5	75,450	3.9	294,255
Total					786,308

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

The annual burden for the information collection requirements in these regulations is estimated at 1,304,157 burden hours (517,849 + 786,308 = 1,304,157). The hours per response estimates are based on our experience with similar programs and information received from industry.

Dated: December 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27255 Filed 12–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6535]

Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff.'' The draft guidance document recognizes the value of standards and encourages the use of appropriate standards to facilitate the evaluation of products regulated by the Center for Biologics Evaluation and Research (CBER). The guidance describes CBER's recommendations on the use of standards in product development and the use of such standards in CBER's managed review process. The draft guidance does not endorse the activities of specific Standards Development Organizations or recommend specific standards for use in regulatory submissions.

DATES: Submit either electronic or written comments on the draft guidance by March 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way: