TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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	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	0.21 (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	0.09 (5 minutes)	1,620
58.81(a)–(c); SOPs	300	301.8	90,540	0.14 (8 minutes)	12,676
58.90(c) and (g); Animal care	300	62.7	18,810	0.13 (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 plus 786,308 equals 1,304,157). The hours per response estimates are based on our experience with similar programs and information received from industry.

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08304 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 (PRA).

DATES: Fax written comments on the collection of information by May 25, 2017.

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 0910–0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: For specific questions for FDA related to this document, contact JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION:

Institutional Review Boards—21 CFR 56.115—OMB Control Number 0910–0130—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes, and decisions made by the IRB, the number of votes on each decision for, against, and abstaining; the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations; and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

The recordkeeping requirement burden is based on the following: The burden for the paragraphs under 21 CFR 56.115 has been considered as one

estimated burden. This burden estimate assumes that there are approximately 2,520 IRBs, that each IRB meets on an average of 14.6 times annually, and that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

In the **Federal Register** of November 1, 2016 (81 FR 75826), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

FDA estimates the burden of this collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 56; subpart D; records and reports	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115	2,520	14.6	36,792	100	3,679,200

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

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08327 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2017–N–1780]

Joint Meeting of the Pediatric Advisory Committee and the Pediatric Ethics Subcommittee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; establishment of a public docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC) and the Pediatric Ethics Subcommittee (PES). The general function of the committees is to provide advice and make recommendations to the Agency on pediatric ethical issues. The meeting will be open to the public. FDA is establishing a docket for public comments on this document.

DATES: The meeting will be held on May 18, 2017, from 8:30 a.m. to 5:30 p.m. The docket number is FDA 2017–N–1780. The docket will close on May 19, 2017. Comments received on or before May 5, 2017 will be provided to the committee. Comments received after the date will be taken into consideration by the Agency.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, section A), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/pacm051817.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

You may submit your comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to make available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submission as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA 2017–N–1780 for the ''Joint Meeting of the Pediatric Advisory Committee and the Pediatric Ethics Subcommittee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this