Description: The data collected by form OCSE–75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV–D of the Social Security Act are required to report program status and accomplishments in an annual narrative report and submit the OCSE–75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
OCSE–75	60	1	60	3,600

Estimated Total Annual Burden Hours: 3,600.

Authority: Title IV–D of the Social Security ACT as required by CFR 45 Section 309.170(b).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–27423 Filed 12–18–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects; Informed Consent; and Institutional Review Boards

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 21, 2020.

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Numbers 0910–0755 and 0910–0130—Revision

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of Institutional Review Boards (IRBs) as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in such investigations. The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

21 CFR Part 50—Protection of Human Subjects

Provisions in 21 CFR part 50 provide for the protection of human subjects involved in FDA-regulated clinical investigations. With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Basic elements of informed consent are set forth in § 50.25 and include, among other things, a statement of the purpose and duration of a subject's participation in the research; a description of the procedures to be followed; identification of any experimental procedures; a description of risks, benefits, and appropriate alternative procedures or treatments; a description of extent to which confidentiality of records identifying the subject will be maintained; certain contact information; and a statement that participation is voluntary and may be discontinued at any time. Additional elements set forth in § 50.25 are required in the informed consent as appropriate. Exceptions to these requirements are governed by § 50.23, which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied; and § 50.24, which covers exception from informed consent requirements for emergency research. In accordance with § 50.27, informed consent must be documented, except as provided in § 56.109(c), which provides for an IRB to waive documentation of informed consent in certain circumstances. Informed consent must be documented using a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. For each clinical investigation reviewed by an IRB, we believe there will typically be one associated written consent form developed by an investigator. In some cases, investigators will seek IRB approval of changes in the research and/or consent form after initial IRB approval. For some multi-institutional clinical investigations, the IRB of each institution involved may separately conduct initial and continuing review of the research, including review of the written consent form to determine

whether it is in accordance with § 50.25. However, in cases where a multi-institutional clinical investigation uses a single IRB review process, there may only be one IRB conducting such reviews.

Finally, additional safeguards are required for children, as prescribed in subpart D (21 CFR parts 50.50 through 50.56) of the regulations.

21 CFR Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibilities of an IRB are set forth in 21 CFR part 56. IRBs serve in an oversight capacity by reviewing, among other things, informed consent documents and protocols for FDA-regulated studies, to make findings required to approve research and document IRB actions. Part 56 also regulates the administrative activities of IRBs reviewing FDA-regulated research including, among other things, identification of types of IRB records that must be prepared and maintained. Required recordkeeping includes documentation pertaining to written procedures, proposals reviewed, committee membership, meeting minutes, actions taken by the IRB, correspondence, as well as other functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for non-compliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

Consolidation of Information Collection Requests

On our own initiative, we are revising the information collection under OMB control number 0910–0130 to include information collection under OMB control number 0910–0755 pertaining to the protection of human subjects, including informed consent and certain IRB requirements. Because of the related nature of the information collections and the applicable regulations in parts 50 and 56, we believe taking this action will improve our operational efficiency.

Description of Respondents: Respondents to the information collection are IRBs that review and approve clinical investigations regulated by the FDA and clinical investigators of such research who obtain informed consent of human subjects prior to research participation.

In the **Federal Register** of August 14, 2019 (84 FR 40421), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Upon our own review, however, we have reorganized and added detail to the notice to describe more clearly the information collection and associated burden. We continue to invite comment.

We estimate the annual burden for the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.113; suspension or termination of research	2,520	1	2,520	*0.5	1,260
56.120(a); IRB response to lesser administration actions for noncompliance	7	1	7	10	70
56.123; reinstatement of an IRB or an institution	1	1	1	5	5
Total					1,335

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (30 minutes).

Based on a review of data, there are currently 2,520 IRBs overseeing FDA-regulated clinical research. After reorganizing the table summarizing estimated annual reporting burden to list only one requirement per row as discussed in the 60-day notice (84 FR 40421), we recognized that some of those regulatory provisions are more appropriately characterized as having associated recordkeeping or third-party disclosure burdens. Therefore, we have revised Tables 1, 2, and 3 accordingly in this notice. We request comments on this estimate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
50.24; exceptions from informed consent for emergency research	8	3	24	1	24
50.27; documentation of informed consent	2,520	40	100,800	*0.5	50,400
56.115; IRB records (documentation of IRB activities)	2,520	14.6	36,792	40	1,471,680
Total					1,626,759

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (30 minutes).

As discussed above, we have reorganized the table to characterize our estimate of burden associated with 50.24 and 50.27 as recordkeeping burdens. We assume each of the 2,520 IRBs meets an average of 14.6 times annually and that approximately 40 hours of person-time per meeting are required to meet the IRB recordkeeping requirements of 21 CFR 56.115. We have reduced the estimate of average burden per response from 100 hours to 40 hours because we believe the original estimate of 100 hours has decreased with the use of electronic recordkeeping and new technologies available to maintain records. We estimate burden associated with recordkeeping responsibilities

under 21 CFR parts 50 and 56 cumulatively, however we have itemized burden associated with certain of the regulatory provisions for purposes of providing a more detailed estimate. We invite comment on burden associated with these information collection requirements.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	*0.5	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived	2,520	2	5,040	*0.5	2,520
56.109(e); written notification to approve or disapprove research	2,520	40	100,800	*0.5	50,400
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16
Total					103,336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (30 minutes).

As discussed above, we have reorganized the table to characterize our estimates of burden associated with 21 CFR 50.25, 56.109(d) and 56.109(e) as disclosure burdens. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under 21 CFR 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: December 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27351 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5585]

Bridging for Drug-Device and Biologic-Device Combination Products; Draft Guidance for Industry; 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 guidance for industry entitled ''Bridging for Drug-Device and Biologic-Device Combination Products.'' This draft guidance, when finalized, will represent the Agency's thinking on how to approach bridging in new drug applications (NDAs) or biologics license applications (BLAs) for drug-device and biologic-device single entity or co-packaged combination products and will help to fulfill the performance goals under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). For the purposes of this guidance, the term *bridging* refers to the process of establishing the scientific relevance of information developed in an earlier phase of the development program or another development program to support the combination product for which an applicant is seeking approval. Once the applicant has established the relevance of such information to (*i.e.,* bridged to) its product, the applicant may be able to leverage that information to streamline the development program.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 2020 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:

- *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 be made 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 submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–5585 for ''Bridging for Drug-Device and Biologic-Device Combination Products.'' 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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential