Compensation Program Act of 2000 (42 U.S.C. 7384–7385) was enacted. This Act established a federal compensation program for employees of the Department of Energy (DOE) and certain of its contractors, subcontractors and vendors, who have suffered cancers and other designated illnesses as a result of exposures sustained in the production and testing of nuclear weapons.

Executive Order 13179, issued on December 7, 2000, delegated authorities assigned to ''the President'' under the Act to the Departments of Labor, Health and Human Services, Energy and Justice. The Department of Health and Human Services (DHHS) was delegated the responsibility of establishing methods for estimating radiation doses received by eligible claimants with cancer applying for compensation. NIOSH is applying the following methods to estimate the radiation doses of individuals applying for compensation.

In performance of its dose reconstruction responsibilities, under the Act, NIOSH is providing voluntary interview opportunities to claimants (or their survivors) individually and providing them with the opportunity to assist NIOSH in documenting the work history of the employee by characterizing the actual work tasks performed. In addition, NIOSH and the claimant may identify incidents that may have resulted in undocumented radiation exposures, characterizing radiological protection and monitoring practices, and identify co-workers and other witnesses as may be necessary to confirm undocumented information. In this process, NIOSH uses a computer assisted telephone interview (CATI) system, which allows interviews to be conducted more efficiently and quickly as opposed to a paper-based interview instrument. Both interviews are voluntary and failure to participate in either or both interviews will not have a negative effect on the claim, although voluntary participation may assist the claimant by adding important information that may not be otherwise available.

There are no changes to the questions contained in the package, or the estimated burden hours. This Information Collection Request (ICR) is being submitted as a reinstatement because the previous ICR expired on April 30, 2018 and the updated ICR was not submitted before the expiration date. NIOSH uses the data collected in this process to complete an individual dose reconstruction that accounts, as fully as possible, for the radiation dose incurred by the employee in the line of duty for DOE nuclear weapons production programs. After dose reconstruction, NIOSH also performs a brief, voluntary final interview with the claimant to explain the results and to allow the claimant to confirm or question the records NIOSH has compiled. This will also be the final opportunity for the claimant to supplement the dose reconstruction record.

At the conclusion of the dose reconstruction process, the claimant submits a form to confirm that the claimant has no further information to provide to NIOSH about the claim at this time. The form notifies the claimant that signing the form allows NIOSH to forward a dose reconstruction report to DOL and to the claimant, and closes the record on data used for the dose reconstruction. Signing this form does not indicate that the claimant agrees with the outcome of the dose reconstruction. The dose reconstruction results will be supplied to the claimant and to the DOL, the agency that will utilize them as one part of its determination of whether the claimant is eligible for compensation under the Act.

Total annualized burden is estimated to be 3900 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Claimant	Initial Interview	3,600	1	1
Claimant	Conclusion form OCAS–1	3,600	1	5/60

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–12972 Filed 6–15–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on formal meetings between FDA and biosimilar biological product sponsors or applicants.

DATES: Submit either electronic or written comments on the collection of information by August 17, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time

at the end of August 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–D–0286 for ''Guidance for Industry: Formal Meetings Between Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 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 Dockets Management Staff. 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 information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: 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: Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants

OMB Control Number 0910–0802—Extension

The Biologics Price Competition and Innovation Act of 2009, the Biosimilar User Fee Act of 2012, and the recent passage of the Biosimilar User Fee Amendments of 2017 (BsUFA II) under Title IV of the Food and Drug Administration Reauthorization Act of 2017, authorizes user fees for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the reauthorized biosimilar user fee program. FDA developed a guidance for industry entitled ''Formal Meetings Between FDA and Biosimilar Biological Products Sponsors or Applicants'' to provide recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) and assist sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products. The guidance describes FDA's current

thinking on how the Agency intends to interpret and apply certain provisions of BsUFA II and provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products. The guidance includes two types of information collections: (1) The submission of a meeting request containing certain information and (2) the submission of the information package(s) that accompany the meeting request. This information collection supports this Agency guidance document.

A. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with CDER or CBER should submit a meeting request to the sponsor's or applicant's application (*i.e.,* investigational new drug application, biologics license application). If there is no application, a sponsor or applicant should submit the request to either the appropriate CDER division director, with a copy sent to the division's chief of project management staff, or to the division director of the appropriate product office within CBER. However, a sponsor or applicant should only submit such a request after first contacting the appropriate review division or the Biosimilars Program staff, CDER, Office of New Drugs, to determine to whom the request should be directed, how it should be submitted, the appropriate format for the request, and to arrange for confirmation of receipt of the request.

Under the guidance, FDA requests that sponsors and applicants incorporate certain information in the meeting request including:

1. Product name,
2. application number (if applicable),
3. proposed proper name or proper name (post licensure),
4. structure,
5. reference product name,
6. proposed indication(s) or context of product development,
7. meeting type being requested (the rationale for requesting the meeting type should be included),
8. a brief statement of the purpose of the meeting, including a brief background of the issues underlying the agenda and, as applicable, a brief summary of completed or planned studies and clinical trials or data the sponsor or applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in the overall development plans,
9. a list of specific objectives/outcomes expected from the meeting,
10. a proposed agenda, including times required for each agenda item,
11. a list of questions grouped by discipline and a brief explanation of the context and purpose of each question,
12. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and consultants,
13. a list of FDA staff, if known, or disciplines asked to participate in the requested meeting,
14. suggested dates and times for the meeting, and
15. the proposed format of the meeting (*i.e.,* face to face meeting, teleconference, or videoconference).

This information is be used by FDA to facilitate formal meetings with biosimilar biological product sponsors.

B. Information Package

FDA requests that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request. FDA recommends that the information packages generally include:

1. Product name and application number (if applicable),
2. proposed proper name or proper name (post licensure),
3. structure,
4. reference product name,
5. proposed indication(s) or context of product development,
6. dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s),
7. a list of all sponsor's or applicant's attendees and consultants with their titles and affiliations who will attend the requested meeting,
8. background that includes a brief history of the development program and the status of product development (*e.g.,* chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable),
9. a brief statement summarizing the purpose of the meeting,
10. the proposed agenda,
11. a list of questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question, and
12. data to support discussion of the listed questions, organized by discipline and question.

The purpose of the meeting package is to provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

Description of Respondents: A sponsor or applicant for a biosimilar biological product who requests a formal meeting with FDA regarding the development and review of a biosimilar biological product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance for Industry: Formal Meetings Between FDA and Biosimilar Biological Product Sponsors or Applicants	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER Meeting Requests	36	2.5	89	15	1,335
CBER Meeting Requests	2	1	2	15	30
CDER Information Packages	29	2.2	64	30	1,920
CBER Information Packages	2	2	4	30	120
Total					3,405

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

Since the last OMB approval there has been an increase in meeting requests with CDER and a corresponding increase in the number of information packages. Accordingly, we have adjusted our estimate of CDER meeting requests upward by six respondents. We attribute this change to an increase in biosimilar product development.

Dated: June 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12968 Filed 6–15–18; 8:45 am]

BILLING CODE 4164–01–P