practice. This study aligns with National HIV/AIDS Strategy 2020 and Healthy People 2020 objectives of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, and reducing HIV-related health disparities. This study also aligns with the Office of Management and Budget's emphasis on application of behavioral insights in that it restructures the context (*i.e.,* after HIV testing) in which health-related decision-making (*i.e.,* health insurance enrollment) occurs in order to promote the selection of beneficial options (*i.e.,* attending HIV-related medical care appointments). This proposed health insurance enrollment assistance study has the potential for widespread health improvements for Black and Hispanic MSM and transgender persons regardless of their HIV status.

At this time, CDC is not partnering with other HHS agencies for this study. However, we have discussed the study with HRSA/HAB and HHS/OD, and plan to apprise CMS and HRSA of the project before implementation and invite CMS and HRSA representatives to serve as consultants. HHS may also direct us to the CMS regional officer for Chicago, Illinois. Additionally, there is the potential to have CMS grantee navigators supplement partner agency navigators during outreach HIV testing events. For this study, CDC is not engaged in research, and therefore not involved in data collection activities. The grantee is responsible for implementing the intervention and collecting data from the proposed 1,000 participants. Thus, CDC will not need an interagency data-sharing agreement if we do consult with HRSA or CMS.

The study will enroll 1,000 participants over 12 months to reach adequate power calculations (500 into the intervention arm, and 500 into the control arm). Approximately 1,500 individuals will need to be screened to identify and enroll 1,000 eligible study participants. After an HIV testing session at an outreach event or clinic visit, partner agency staff will invite individuals to participate in the study. If individuals are interested, staff will screen individuals for eligibility using the Participant Eligibility Form (Attachment 5) which will take approximately 5 minutes to complete. If they are determined eligible to participate, and still interested in participating, the individual will complete an Informed Consent Form (Attachment 6), which will take approximately 10 minutes to complete, and the Participant Enrollment Form (Attachment 7), which will take approximately 35 minutes to complete. The total estimated annualized hourly burden anticipated for this study is 875 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Study participant	Participant Eligibility Form (Att 5)	1,500	1	5/60
Study participant	Informed Consent Form (Att 6)	1,000	1	10/60
Study participant	Participant Enrollment Form (Att 7)	1,000	1	35/60

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–0530]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) Dose Reconstruction Interviews and Forms to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 20, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

EEOICPA Dose Reconstruction Interviews and Forms, OMB No. 0920–0530, expires 04/30/2018—Reinstatement without change—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On October 30, 2000, the Energy Employees Occupational Illness

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.

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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