protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product that FDA regulates under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) requesting special protocol assessment.

Burden Estimate: Table 1 provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

Notification for a Carcinogenicity Protocol: Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 188 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 105 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment: Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 108 requests for special protocol assessment per year from approximately 105 sponsors. CBER estimates that it will receive approximately eight requests from approximately eight sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on our experience with these submissions, we estimate approximately 15 hours on average would be needed per response.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification for Carcinogenicity Protocols	106	1.78	189	8	1,510
Requests for Special Protocol Assessment Reports	113	1.66	116	15	1,740
Total			305		3,250

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

The information collection reflects an adjustment in burden by 608 hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: December 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28408 Filed 1–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Countermeasures Injury Compensation Program OMB No. 0915–0334—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than February 3, 2020.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Countermeasures Injury Compensation Program OMB No. 0915–0334—Extension.

Abstract: This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). The CICP, within the Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, HRSA, administers this compensation program as specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act).

The Secretary of HHS (Secretary) can issue a PREP Act declaration. When issued, the purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. The Secretary's declaration may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures (*e.g.,* anthrax vaccine) to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

A 60-day notice was published in the **Federal Register** on July 16, 2019, vol. 84, No. 136; pp. 33954–55. There were no public comments.

Need and Proposed Use of the Information: The CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors.

To determine whether a requester is eligible for Program benefits (compensation) for a countermeasure injury, the CICP staff must review the Request for Benefits Package (RFB) that includes the following:

(1) Request for Benefits Form and Supporting Documentation

The Request for Benefits Form and supporting documentation initiates the CICP claims review process. They also serve as the CICP's mechanism for gathering required information about the requester, documenting the use or administration of a countermeasure, and obtaining medical information about the countermeasure recipient.

(2) Authorization for Use or Disclosure of Health Information Form (Authorization Form)

The requester completes the Authorization Form and permits medical providers to disclose the countermeasure recipient's health information via medical records to the CICP for determining eligibility for CICP benefits.

(3) Additional Documentation and Certification

During the eligibility review, the CICP provides requesters with the opportunity to supplement their RFB with additional medical records and supporting documentation before the Program makes a final decision. The CICP asks requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case. After the CICP makes a final decision on a case, there are no other opportunities for a requester to submit additional medical records or supporting documents.

(4) Benefits Package and Supporting Documentation

A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive payment for unreimbursed medical expenses and/or lost employment income accrued prior to the injured countermeasure recipient's death. These documents ask the requester to submit documentation of the countermeasure recipient's unreimbursed medical expenses and lost employment income. If death was the result of the administration or use of the countermeasure, certain survivor(s) of eligible deceased countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits (42 CFR 110.33). These documents request additional information, such as a marriage license, from the requester to prove that they are a survivor of the deceased countermeasure recipient.

The RFB that the CICP sends to requesters who may be eligible for compensation includes certification forms and instructions outlining the supporting documentation needed to determine the types and amounts of benefits. This documentation is required under 42 CFR 110.60–110.63 of the CICP's implementing regulation to enable the Program to determine the types and amounts of benefits the requester may be eligible to receive.

Likely Respondents: Countermeasure recipients are the most likely respondents to this **Federal Register** notice regarding the CICP information collection request because the CICP reviews, and if eligible, compensates countermeasure recipient injury claims.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Request for Benefits Form and Supporting Documentation	100	1	100	11	1,100
Authorization for Use or Disclosure of Health Information Form	100	1	100	2	200
Additional Documentation and Certification	30	1	30	.75	22.5
Benefits Package and Supporting Documentation	30	1	30	.125	3.75
Total	260		260		1,326.25

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–28367 Filed 1–2–20; 8:45 am]

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