Respondents to this collection of information are generic animal drug applicants. Based on FDA’s data base system, there are an estimated 20 sponsors of new animal drugs potentially subject to AGDUF A.

Dated: August 29, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–21177 Filed 9–1–16; 8:45 am]

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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with 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.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the ICR 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 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 an extension of OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP). The CICP, within the Health Resources and Services Administration (HRSA), administers the compensation program specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act). 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 (all of these parties may be “requesters”). A declaration is issued by the Secretary of the Department of Health and Human Services (Secretary). 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. In addition, the Secretary, through a declaration, may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

To determine whether a requester is eligible for CICP benefits (compensation) for the injury, the CICP must review the Request for Benefits Package, which includes the Request for Benefits Form and Authorization for Use or Disclosure of Health Information Form(s), as well as the injured countermeasure recipient’s medical records 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 be eligible to receive medical benefits and/or benefits for lost employment income accrued prior to the injured countermeasure recipient’s death. If death was the result of the administration or use of the countermeasure, certain survivor(s) of deceased eligible countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits. 42 CFR 110.33. The death benefit is calculated using either the “standard calculation” or the “alternative calculation.” The “standard calculation” is based on the death benefit available under the Public Safety Officers’ Benefits (PSOB) Program. 42 CFR 110.82(b). The “alternative calculation” is based on the deceased countermeasure recipient’s income and is only available to the recipient’s dependent(s) younger than age 18 at the time of the deceased countermeasure recipient’s death. 42 CFR 110.82(c).

Approval is requested for the required continued information collection via the Request for Benefits Package and for the continued use of CICP’s mechanisms for obtaining medical documentation and supporting documentation collection. During the eligibility review, the CICP provides requesters with the opportunity to supplement their Request for Benefits with additional medical records and supporting documentation before a final determination is made. 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.

Approval is requested for the continued use of the benefits documentation package that the CICP sends to requesters who may be eligible for compensation, which includes certification forms and instructions outlining the documentation needed to determine the types and amounts of benefits. This documentation is required under 42 CFR 110.61–110.63 of the CICP’s implementing regulation to enable the CICP to determine the types and amounts of benefits the requester may be eligible to receive.

Need and Proposed Use of the Information: The information collected from requesters provides data and documentation that is needed for the CICP to determine: (1) The requester’s eligibility to receive benefits; and (2) if applicable, the type and amount of benefits that may be awarded.

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.

<table>
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<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
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</tbody>
</table>

* The number 100 represents an estimate of individuals applying for Program benefits. The 4 documents are required of the same 100 individuals or subset of the 100 individuals.
SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Cancer Institute (NCI) and the Clinical Center (CC), National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an exclusive license to Advanced Imaging Projects, LLC, a company having a place of business in Boca Raton, FL, to practice the inventions embodied in the following patent applications:

Intellectual Property


PCT Application No. PCT/US2005/027866, filed 3 August 2005, now abandoned, titled “Integrin αvβ3 antagonists for use in imaging and therapy” (HHS Ref. No.: E–170–2004/0–PCT–02);


Germany Patent No. 602005028137.1, titled “Integrin αvβ3 antagonists for use in imaging and therapy” filed 4 March 2007, issued 18 May 2011 (HHS Ref. No.: E–170–2004/0–DE–05);


The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to expediently commercialize results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT:

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

Dated: August 29, 2016.

Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.