claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

**Form FDA 3728, Animal Generic User Fee Act Cover Sheet—21 U.S.C. 379j–21 OMB Control Number 0910–0632—Extension**

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the AGDUFA Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Form FDA No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 3728 | 20 | 2 | 40 | .08 (5 min.) | 3.2 |

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

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 AGDUFA.

Dated: August 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–21177 Filed 9–1–16; 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

**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 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.

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 | 1100 |
| 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 | *100 | ..... | 100 | ..... | 1326.25 |

*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.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2016–21168 Filed 9–1–16; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of Exclusive Patent License: Development of Integrin αvβ3 Antagonists for Use in Imaging and Therapy

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**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**

U.S. Patent No. 7,300,940, filed 4 August 2004, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' (HHS Ref. No.: E–170–2004/0–US–01);

PCT Application No. PCT/US2005/027868, filed 3 August 2005, now abandoned, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' (HHS Ref. No.: E–170–2004/0–PCT–02);

Switzerland Patent No. 1781622, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' filed 4 March 2007, issued 18 May 2011 (HHS Ref. No.: E–170–2004/0–CH–04);

Germany Patent No. 602005028137.1, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' filed 4 March 2007, issued 18 May 2011 (HHS Ref. No.: E–170–2004/0–DE–05);

France Patent No. 1781622, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' filed 4 March 2007, issued 18 May 2011 (HHS Ref. No.: E–170–2004/0–FR–060); and

Ireland Patent No. 1781622, titled ''Integrin α-v β-3 antagonists for use in imaging and therapy'' filed 4 March 2007, issued 18 May 2011 (HHS Ref. No.: E–170–2004/0–IE–07).

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective exclusive license may be worldwide, and the field of use may be limited to ''Conjugate of Alpha-V beta-3 antagonist NIH–CC–013 for theranostic application to diagnose, prevent and treat oncological, infectious, ocular and cardiovascular disorders.''

**DATES:** Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before September 19, 2016 will be considered.

**ADDRESSES:** Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Jaime M. Greene, M.S., Senior Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD 20850; telephone: 240–276–6633; email: *greenejaime@mail.nih.gov.*

**SUPPLEMENTARY INFORMATION:** This technology concerns small molecule compositions that are antagonists for the receptor integrin αvβ3. Integrins are functional molecules for cell adhesion activity that are expressed by the majority of normal and cancer cells. They are trans-membrane heterodimer receptors that include two subunits, α and β chains, that primarily allow cell adhesion to extracellular matrix components such as fibrillar collagen, vitronectin and osteopontin. This technology may be useful for the development of diagnostics and therapeutics for cancers and other conditions involving the integrin αvβ3.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: August 29, 2016.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2016–21113 Filed 9–1–16; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** 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 achieve expeditious commercialization of 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:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the National Heart, Lung and Blood Institute, Office of Technology Transfer and Development, National Institutes of Health, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** Technology descriptions follow.

**Microscopy Systems for Instant Internal Reflection Fluorescence/ Structured Illumination**

*Description of Technology:* Structured illumination microscopy (SIM) is a method that uses sharply patterned light and post-processing of images to enhance image resolution (in its linear form, doubling resolution). In traditional SIM, a series of images are acquired with a camera and computationally processed to improve resolution. This implementation of SIM has also been combined with total internal reflection fluorescence (TIRF), but the implementation still requires raw images relative to normal TIRF microscopy, thereby slowing acquisition 9-fold relative to conventional, diffraction-limited imaging. This TIRF/