DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; RFA AA19–004 Specialized Alcohol Research Centers.

Date: August 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Conference Rooms B & C, Bethesda, MD 20817.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2136, Rockville, MD 20852, 301–443–0800, bbuzas@mail.nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: RP2 AAV Vectors for Treating X-Linked Retinitis Pigmentosa

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the SUPPLEMENTARY INFORMATION section of this notice to IVERIC bio, Inc. located in New York, NY.

DATES: Only written comments and/or applications for a license which are received by the National Eye Institute c/o National Cancer Institute’s Technology Transfer Center on or before June 3, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702, Telephone: (240)–276–5530, Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

Intellectually Property


With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “Human therapeutics for treating x-linked retinitis pigmentosa: The license will also be limited by licensed products covered by patent rights that pertain to AAV-mediated gene therapy delivering an RP2 transgene.”

This technology discloses adenovirus vectors comprising nucleotide sequences encoding RPGR–ORF15 or RP2 and related pharmaceutical compositions. It also discloses methods of treating or preventing x-linked retinitis pigmentosa, increasing photoreceptor number in the retina of a mammal, and increasing visual acuity of a mammal using the vectors and pharmaceutical compositions.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Eye Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license
DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Accreditation of Commercial Testing Laboratories and Approval of Commercial Gaugers


ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the Federal Register to obtain comments from the public and affected agencies. Comments are encouraged and must be submitted (no later than July 16, 2019) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0053 in the subject line and the agency name. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) Email. Submit comments to: CBP_PRA@cbp.dhs.gov.
(2) Mail. Submit written comments to CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177. Telephone number 202–325–0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at https://www.cbp.gov/.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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; (2) the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to 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. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Accreditation of Commercial Testing Laboratories and Approval of Commercial Gaugers.

OMB Number: 1651–0053.

Form Number: Form 6478.

Abstract: Commercial laboratories seeking accreditation or approval must provide the information specified in 19 CFR 151.12 to Customs and Border Protection (CBP), and Commercial Gaugers seeking CBP approval must provide the information specified under 19 CFR 151.13. This information may be submitted on CBP Form 6478. After the initial approval and/or accreditation, a private company may “extend” its approval and/or accreditation to add facilities by submitting a formal written request to CBP. This application process is authorized by Section 613 of Public Law 103–182 (NAFTA Implementation Act), codified at 19 U.S.C. 1499(b), which directs CBP to establish a procedure to accredit privately owned testing laboratories. The information collected is used by CBP in deciding whether to approve individuals or businesses desiring to measure bulk products or to analyze importations. Instructions for completing these applications are accessible at: http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories. CBP Form 6478 is accessible at: http://www.cbp.gov/sites/default/files/documents/CBP%20Form%206478_0.pdf.

Current Actions: This submission is being made to extend the expiration date with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Applications for Commercial Testing and Approval of Commercial Gaugers:

Estimated Number of Annual Respondents: 8.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 8.

Estimated Time per Response: 1.25 hours.

Estimated Total Annual Burden Hours: 10.

Record Keeping Associated with Applications for Commercial Testing and Approval of Commercial Gaugers:

Estimated Number of Respondents: 180.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 180.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 180.

Dated: May 14, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.