

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: Center for Scientific Review Special Emphasis Panel, Targeting Technologies.

Date: August 5, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Steven J. Jullo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7849, Bethesda, MD 20892, (301) 435-2810, zullost@scr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 1, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-15538 Filed 8-4-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development and Use of Cripto-1 as a Biomarker and Treatment for Neurodegenerative Disease

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that 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 U.S. Patent Application 60/508,750, filed October 3, 2003 [DHHS Ref. E-075-2003/0-US-01] and PCT Application PCT/US04/32649 [DHHS Ref. E-075-2003/0-PCT-02], entitled Use of Cripto-1 as a Biomarker for Neurodegenerative Disease and Method of Inhibiting Progression Thereof, to Neuronascent, Inc., which is located in Clarksville, Maryland. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the development and use of Cripto small molecule inhibitors to treat and prevent Alzheimer's disease in humans.

DATES: Only written comments and/or applications for a license, which are received by the NIH Office of Technology Transfer on or before October 4, 2005 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Michelle A. Booden, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; telephone: (301) 451-7337; Facsimile: (301) 402-0220; e-mail: boodenm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The technology relates to another use of Cripto-1 as a biomarker and possible therapeutic target for a variety of neurodegenerative diseases, including NeuroAids, Alzheimer's disease, Multiple Sclerosis, Amyotrophic Lateral Sclerosis, Parkinson's disease and encephalitis. Cripto-1 appears to be overexpressed by 20-fold or more in NeuroAids and as such, may be enhanced in other inflammatory neurological diseases, and thus assist in the early detection of neurological changes associated with these diseases, as well as a possible therapeutic target for slowing progression.

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 404.7. The prospective exclusive license may be granted unless within sixty (60) 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 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. 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: July 28, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05-15540 Filed 8-4-05; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234)—Revision

The Drug Addiction Treatment Act of 2000 (“DATA,” Pub. L. 106-310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers.

To implement these new provisions, SAMHSA developed a notification form (SMA-167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.*, independent physicians and physicians in group practices (as defined under section 1877(h)(4) of the Social Security Act) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information

needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner’s registration under 21 U.S.C. 823(f).

Practitioners may use the form for two types of notification: (a) New, and (b) immediate. Under “new” notifications, practitioners may make their initial waiver requests to SAMHSA. “Immediate” notifications inform SAMHSA and the Attorney General of a practitioner’s intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii).

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; e-mail address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal;

certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician Locator.

Since July 2002, SAMHSA has received just over 6,000 notifications and has certified over 5,500 physicians. Eighty-one percent of the notifications were submitted by mail or by facsimile, with approximately twenty percent submitted through the Web based online system. Approximately 60 percent of the certified physicians have consented to disclosure on the SAMHSA Buprenorphine Physician Locator.

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of respondents	Responses per respondent	Burden per response (hr)	Total burden (hrs)
Initial Application for Waiver	2,000	1	.083	166
Notification to Prescribe Immediately	50	1	.083	4
Total	2,050	170

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 29, 2005.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 05-15500 Filed 8-4-05; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Public Workshop: Privacy and Technology: Government Use of Commercial Data for Homeland Security

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice announcing public workshop.

SUMMARY: The Department of Homeland Security Privacy Office will host a public workshop, “Privacy and Technology: Government Use of Commercial Data for Homeland Security,” to explore the policy, legal, and technology issues associated with the government’s use of personally identifiable commercial data in protecting the homeland.

DATES: The workshop will be held on September 8, 2005, from 8 a.m. to 4:30 p.m. and on September 9, 2005, from 8:30 a.m. to 12:30 p.m.

ADDRESSES: The Privacy and Technology Workshop will be held in the auditorium at the DHS Offices at the GSA Regional Headquarters Building located at 7th and D Streets, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Toby Milgrom Levin, Robyn Kaplan, Kenneth Mortensen, or Peter Sand at Privacy Workshop, Privacy Office, Department of Homeland Security, Arlington, VA 22202, by telephone 571-227-3813, by facsimile 571-227-4171, or by e-mail at privacyworkshop@dhs.gov.

SUPPLEMENTARY INFORMATION:

Workshop Goals

The Department of Homeland Security (DHS) Privacy Office is holding