Dated: March 18, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–6607 Filed 3–23–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Methods and Compositions for the Promotion of Hair Growth Utilizing Actin Binding Peptides

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 60/351,386 (re-filed), PCT Patent Application No. PCT/US03/01973, filed January 22, 2003 [DHHS Ref. E–053–2002/0–PCT–02], entitled ''Methods and Compositions for the Promotion of Hair Growth Utilizing Actin Binding Peptides,'' to EGB Advisors, LLC, which is located in San Francisco, California. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide (with the exception of China, Hong Kong and Taiwan) and the field of use may be limited to the use of actin binding proteins for the development of a topical hydrogel treatment for alopecia to promote hair growth.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 24, 2004, 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: Jesse S. Kindra, J.D., M.S., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5559; Facsimile: (301) 402–0220; E-mail: *kindraj@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The technology describes methods and compositions for treating a subject (human or animal) suffering from hair loss. More specifically, the technology relates to the discovery that actin binding peptides promote hair growth. In one example, the technology describes the exogenous delivery of a seven amino acid peptide of Thymosin-4 to promote hair growth.

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: March 7, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–6609 Filed 3–23–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Public Comment on the Nomination for Ocular Toxicity Test Methods and Related Activities and Request for Data on Chemicals Evaluated by *In Vitro* or *In Vivo* Ocular Irritancy Test Methods

SUMMARY: On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), NICEATM requests (1) public comment on four test methods for ocular toxicity and related activities nominated to the ICCVAM by the U.S. Environmental Protection Agency (EPA), (2) public comment on ICCVAM's recommended actions for the nomination, and (3) data from completed studies on chemicals and products tested for ocular irritancy using *in vitro* and/or *in vivo* test methods. This data will be used to (1) evaluate the validation status of existing *in vitro* test methods for ocular irritancy/corrosion and (2) develop a list of substances with high quality *in vivo* data that can be considered as reference chemicals for future validation studies.

NICEATM welcomes data generated using standardized *in vitro* test methods used to identify severe, moderate, mild, or non-irritating substances. Test methods for identifying severe (irreversible) ocular irritation/corrosion for which data are sought include, but are not limited to the four methods nominated by the EPA: (1) The Bovine Corneal Opacity and Permeability (BCOP) test, (2) the Isolated Rabbit Eye (IRE) test or the Rabbit Enucleated Eye Test (REET), (3) the Isolated Chicken Eye (ICE) test or the Chicken Enucleated Eye Test (CEET), and (4) the Hen's Egg Test—Chorion Allantoic Membrane (HET–CAM). In addition, high quality data from standardized ocular irritancy test methods using rabbits (*e.g.*, EPA 1998; UN 2003) and *in vivo* data generated from procedures/protocols that might alleviate or reduce pain and suffering (*e.g.*, topical and systemic analgesics) in test animals are requested.

Background Information

The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) unanimously recommended at its meeting in August 2003 that NICEATM focus efforts on test methods for ocular irritancy and possibly hold a workshop and/or develop a background document on available methods. In October 2003, the EPA nominated the following activities to ICCVAM: (1) Evaluate the validation status of four *in vitro* ocular toxicity test methods: the BCOP, IRE or the REET, ICE or CEET, and HET–CAM, (2) identify and develop *in vivo* ocular toxicity reference data to support the validation of *in vitro* test methods, (3) explore ways of alleviating pain and suffering from current *in vivo* ocular toxicity testing, and (4) review the state of the science and the availability of *in vitro* test methods for assessing mild or moderate ocular irritants. ICCVAM endorsed the review of the methods as a high priority and recommended that NICEATM develop Background Review Documents for BCOP, IRE, ICE, and HET–CAM. ICCVAM also recommended that NICEATM convene an expert panel to independently review the validation status of these four methods and propose standardized protocols for these test methods.

As part of the nomination review process, the NICEATM invites public comments on the EPA nomination to ICCVAM and the ICCVAM's recommended actions. In addition, ICCVAM and NICEATM are collaborating with the European Center for the Validation of Alternative Methods (ECVAM) to evaluate the validation status of *in vitro* methods for assessing ocular irritation/corrosion. In response to the SACATM recommendation, the EPA nomination and ICCVAM's recommended actions, and the NICEATM/ICCVAM collaboration with ECVAM, NICEATM also requests the submission of data from completed studies on chemicals and products tested for ocular irritancy using *in vitro* and/or *in vivo* test methods. This data will be used to evaluate the validation status of existing *in vitro* test methods for ocular irritancy/corrosion and to develop a list of substances with high quality *in vivo* data that can be considered as reference chemicals for future validation studies. Information on the expert panel evaluation(s) will be announced in a future **Federal Register** notice.

Public Comment and Submission of Chemical and Protocol Information and Test Data

Public comment and data and other information submitted in response to this notice should be sent to NICEATM (Dr. William S. Stokes, Director, NICEATM, NIEHS, 79 T.W. Alexander Drive, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, *iccvam@niehs.nih.gov*) and received by May 24, 2004. Data and other information received by this date will be forwarded to the ICCVAM and the ICCVAM Ocular Toxicity Working Group (OTWG) for their consideration. Data and other information received after this date will be periodically compiled and added to the database maintained by NICEATM. All information submitted in response to this notice will be made publicly available upon request to NICEATM.

When submitting data or information on protocols, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable). NICEATM prefers data to be submitted as copies of pages from applicable study notebooks and/or study reports, if available. Each submission for a chemical should preferably include the following information, as appropriate:

- Common and trade name;
- Chemical Abstracts Service Registry Number (CASRN);
- Chemical and/or product class;
- Commercial source;
- *In vitro* test protocol used;
- Rabbit eye test protocol used;
- Human eye test protocol used;
- Individual animal/human or *in vitro* responses at each observation time (*i.e.*, raw data);
- The extent to which the study complies with national/international Good Laboratory Practice (GLP) guidelines;
- Date and testing organization.

Those persons submitting data on chemicals tested for ocular irritancy in rabbits are referred to the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov/methods/eyeirrit.htm*) for an example of the type of experimental animal study information and data requested in this notice.

In Vitro Ocular Irritancy Chemical Tests: BCOP, HET–CAM, ICE, and IRE

NICEATM welcomes public comment on and the submission of data from the four *in vitro* test methods used to identify severe (irreversible) ocular irritation/corrosion nominated by the EPA: BCOP, HET–CAM, ICE, and IRE. This information will be used to evaluate the validation status of these test method protocols and to identify any additional development and/or validation that might be helpful in advancing the usefulness of the proposed test methods. ICCVAM anticipates recommending a standardized protocol for each of the four test methods. ICCVAM also will use existing data and protocols as the basis for development of proposed performance standards that structurally and functionally similar test methods should meet or exceed. Because test methods for identifying severe eye irritants/corrosives are of high priority, NICEATM especially requests data on chemicals identified by these four methods as severe irritants, although data on mildly irritating and non-irritating substances also are welcome.

Other _In Vitro_ Ocular Irritancy Methods

NICEATM also requests the submission of data and information for standardized *in vitro* ocular irritancy methods, other than the four identified above, and methods that might accurately identify non-irritating and mild to moderate irritants. Detailed test method protocols and other related information for these potential test methods should be submitted along with the data.

In Vivo Test Methods for Ocular Irritancy

NICEATM requests the submission of high quality *in vivo* data that might be used to identify appropriate reference chemicals for future validation studies of *in vitro* ocular irritancy test methods. This data would be used to construct a database of *in vivo* data to assess interlaboratory variability, as well as to support validation efforts. Data are sought from studies conducted to comply with Federal or other national/international testing requirements, but may not be publicly available because: (1) The data were submitted to regulatory authorities, but are proprietary and cannot be released to the public by regulatory authorities or (2) there is no requirement to submit the data to regulatory authorities. In addition to data from studies in animals, NICEATM also welcomes the submission of data from human studies, including any human post-marketing or occupational exposure/surveillance data that might be available.

Procedures for Reducing or Eliminating Pain and Suffering during _In Vivo_ Ocular Irritancy Testing

NICEATM requests the submission of information and data from *in vivo* methods, procedures, and/or strategies that may reduce or eliminate the pain and suffering associated with current *in vivo* eye irritation methods, such as those using topical or systemic analgesics.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM promotes the development, validation, evaluation, and regulatory acceptance of toxicological test methods that improve agencies' ability to make decisions on health risks, while refining, reducing and replacing animal use wherever possible.

The ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM provides scientific support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and

NICEATM can be found at the following Web site: *http://iccvam.niehs.nih.gov.*

References

EPA 1998. Health Effects Test Guidelines, OPPTS 870.2500, Acute Eye Irritation, EPA 712–C–98–195. Available: *http://www.epa.gov.opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870-2400.pdf.*

UN. 2003. Globally Harmonized System of Classification and Labelling of Chemicals (GHS). (ST/SG/AC.10/30). United Nations, New York and Geneva. Available: *http://www.unece.org/trans/danger/publi/ghs/officialtext.html.*

Dated: March 15, 2004.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–6487 Filed 3–23–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Funding Opportunity Title: Notice of Funding Availability (NOFA) for the Drug-Addiction-Treatment-Act-of-2000 (DATA) (Title XXXV of the Children's Health Act of 2000) Physician Clinical Support System (Short Title: DATA Physician Clinical Support System)

Announcement Type: Initial.

Funding Opportunity Number: TI 04–005.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Due Date for Applications: June 2, 2004.

(**Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due August 1, 2004.)

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), announces the availability of FY 2004 funds for the Drug-Addiction-Treatment-Act-of-2000 (DATA) (Title XXXV of the Children's Health Act of 2000) Physician Clinical Support System (Short Title: DATA Physician Clinical Support System). A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.grants.gov.*

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grants Program Announcement (INF–04 PA (MOD)), and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The INF–04 PA (MOD) describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the DATA Physician Clinical Support System. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse service systems to support effective programs and services. Additional instructions and specific requirements for this funding opportunity are described below.

I. Funding Opportunity Description

Authority: Section 509 of the Public Health Service Act, as amended and subject to the availability of funds.

The purpose of the DATA Physician Clinical Support System cooperative agreement is to develop a coordinated, clinical support program for physicians who are treating addicted patients with buprenorphine products. The target participants for the clinical support system are primary care physicians, pain specialists, psychiatrists and other non-addiction medical practitioners, who are often reluctant to treat addicted patients and are not as familiar with opioid addiction treatment as addictions specialists are. However, addictions specialists will also be encouraged to participate in the DATA Physician Clinical Support System or to serve as mentors.

Applicants are expected to develop a coherent, well-designed program to assist physicians in developing the skills and confidence to treat addicted patients, thereby reducing resistance and barriers to the availability of treatment. By enlisting the assistance of professional medical groups and other organizations, the grantee will offer physicians the information and consultation they need to provide safe and effective buprenorphine treatment.

Applicants must select activities from the following list of infrastructure development activities, as appropriate to their proposed project:

- Provider/network development (*i.e.*, physician clinical support network/system development to inform physicians of established standards of care);
- Organizational/structural change (*e.g.*, to increase access to and efficiency of services);
- Development of the physician workforce;
- Development of interagency coordination mechanisms (between national professional medical organizations or related organizations); and
- Quality improvement efforts.

Applicants must demonstrate the ability to provide consultative services, telephone consultation, on-site training, observation of practice, and peer mentoring to physicians treating patients for opioid addiction. Applicants may propose other activities, such as conducting a limited number of regional meetings or online Web conferences to improve physician workforce performance.

Physician support activities must focus on the following content areas:

- Assessment and diagnosis using the *Diagnostic and Statistical Manual, Fourth Edition, Text Revision* (*DSM–IV–TR*);
- Induction, maintenance, and detoxification protocols;
- Strategies to avoid complications and treat them;
- Ancillary medications;
- Recommended visit and monitoring schedules;
- Special psychosocial strategies on motivating patients, setting limits, or implementing contingency plans;
- Medically supervised withdrawal and opioid withdrawal scales;
- Referrals to counseling, other ancillary services, or self-help groups;
- Diagnosis and treatment of psychiatric co-morbidities or co-occurring disorders, including, but not limited to, chronic pain, poly-substance abuse, hepatitis C and HIV disease;
- HIV screening, counseling, testing, and referrals;
- Referrals to higher levels of care;
- Special needs patients, including pregnant, adolescent, and elderly patients; and
- Important patient recovery indicators.

Background: The need for medication-assisted treatment for opioid addiction greatly exceeds the Nation's treatment capacity. To address this long-standing problem, the Drug Addiction Treatment Act of 2000 (DATA) was enacted to allow trained, qualified physicians to prescribe specifically approved narcotic medications for the treatment of opioid addiction in their offices or settings outside traditional opioid treatment programs.

The Food and Drug Administration approved two brand-name medications containing buprenorphine for this treatment in 2002. SAMHSA was assigned responsibility to assist with training physicians under DATA. Approximately 4,000 physicians have been trained and 2,500 are approved to prescribe these medications. Yet, the stigma of addiction tends to discourage primary care physicians from obtaining training and treating this population.