

Dated: March 18, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory
Committee Policy.

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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.

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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.