Revised Draft Agenda

Scientific Advisory Committee on Alternative Toxicological Methods October 20, 2004

U.S. Environmental Protection Agency, Building C, Room C111 (Auditorium sections A. and B), 109 T.W. Alexander Drive, Research Triangle Park, NC 27709. (A photo ID is required to access the EPA campus.)

8:30 a.m.

- Call to Order and Introductions
- Welcome and Remarks from the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP)
- Welcome and Remarks from the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Chair
- Update on Activities of the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and ICCVAM
- Update on the European Center for the Validation of Alternative Methods (ECVAM) Workshop Recommendations and Validation Studies
- Evaluation of the Under-Prediction Rate for the *in vivo* Rabbit Dermal Irritation Test
  - Public Comment
- Preliminary Evaluation of the Under-Prediction Rate for the *in vivo* Rabbit Ocular Irritation Test
  - Public Comment

12 p.m.: Lunch Break (on your own, the EPA campus has a cafeteria)

1 p.m.

- ICCVAM Nominations
  - Public Comment
- NTP Roadmap
  - Public Comment
- ICCVAM Perspectives on Proposed OECD Draft guidance Document on the Validation and International Acceptance of New or Updated Test methods for Hazard Assessment (Guidance Document 34)
- General Discussion

4:30 p.m.: Adjourn

Dated: October 8, 2004.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–23559 Filed 10–20–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Human Parvovirus B19 Vaccine

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

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 (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in PCT/US89/04948 filed November 14, 1989, and National Stage filed in Australia (patent no. 631159), Canada (patent no. 1284268), Israel (patent no. 92298) and Japan (patent no. 2755817), entitled ''Parvovirus Capsids''; U.S. patent no. 5,508,186, U.S. patent no. 6,132,732, U.S. patent no. 6,001,371, U.S. patent no. 5,827,647, entitled ''B19 Parvovirus Capsids'' ; U.S. patent no. 5,916,563, U.S. patent no. 6,558,676 entitled ''Parvovirus Capsids''; and PCT/NL90/00130 filed September 11, 1990, and National Stage filed in Europe (patent no. 0491824), Austria (patent no. 122395), Denmark (patent no. 0491824), Germany (patent no. 69019359), Netherlands (patent no. 8902301), Spain (patent no. 2073036) and United States (patent nos. 6,204,044, 6,287,815 and 6,379,885), entitled ''Human Parvovirus B19 Proteins and Virus-like Particles, Their Production and Their Use in Diagnostic Assays and Vaccines'' to Viral Antigens, Inc., having a place of business in Memphis, Tennessee. The patent rights in these inventions have been assigned or exclusively licensed to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before January 19, 2005, will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Susan Ano, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; e-mail: *anos@od.nih.gov*; telephone: (301) 435–5515; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: This technology describes a method of producing non-infectious recombinant human parvovirus B–19 capsids composed of viral proteins VP1 and VP2 or VP2. The technology further relates to diagnostic assays utilizing the recombinantly produced parvovirus capsid proteins, or antibodies to such proteins. The technology also describes a vaccine effective against parvovirus B19 infection, consisting of the recombinant capsid proteins. Data from the inventors show that the configuration of the vaccine optimal for eliciting neutralizing antibodies comprises approximately twenty five percent (25%) VP1 and seventy five percent (75%) VP2. In another embodiment, the technology describes the use of parvovirus B19 viral capsids as a gene delivery system for proteins.

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 90 days from the date of this published notice, 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.

The field of use may be limited to development of vaccines for parvovirus B19.

The licensed territory will be worldwide exclusive.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: October 14, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–23561 Filed 10–20–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Directorate of Science and Technology

[Docket No. DHS–2004–0008]

Notice of Meeting of Homeland Security Science and Technology Advisory Committee

AGENCY: Office of the Under Secretary for Science and Technology, DHS.

ACTION: Notice.

SUMMARY: The Homeland Security Science and Technology Advisory