DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Center for Scientific Review Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Center for Scientific Review Advisory Committee.

Date: May 14–15, 2001.

Time: 8:30 a.m. to 1 p.m.

Agenda: Discussion of activities to evaluate organization and function of the Center for Scientific Review.

Place: National Institutes of Health, Two Rockledge Center, Conference Room 9100, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Robert W. Eisinger, PhD, Associate Director, Office of Planning, Analysis and Evaluation, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3016, MSC 7776, Bethesda, MD 20892, 301–435–1111.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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: March 15, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–7203 Filed 3–22–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 14, 2001, 8 a.m. to March 14, 2001, 3 p.m., NIH, Rockledge 2, Bethesda, MD 20892 which was published in the **Federal Register** on February 23, 2001, 66 FR 11307–11308.

The meeting will be held on April 9, 2001, from 2 p.m. to 3:30 p.m. The location remains the same. The meeting is closed to the public.

Dated: March 15, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–7219 Filed 3–22–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Treating Inflammatory Bowel Disease Using Antibodies Against Interleukin-Twelve (IL–12)

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), announces that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in U.S. Patent 5,853,697 entitled, ''Methods of Treating Established Colitis Using Antibodies Against IL–12,'' which was filed on October 25, 1995 and issued on December 29, 1998, and corresponding foreign patent applications, to Centocor, Inc. which is located in Malvern, PA. The patent rights in these inventions have been assigned to the United States of America.

The prospective co-exclusive license territory will be worldwide and the field of use will be therapeutics for the treatment of inflammatory bowel disease, including but not necessarily limited to colitis and Crohn=s disease.

DATES: Only *written* comments and/or license applications which are received by the National Institutes of Health on or before May 22, 2001 will be considered.

ADDRESSES: Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated co-exclusive license should be directed to: Richard U. Rodriguez, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 496–7056, X287; Facsimile: (301) 402–0220; E-mail: rodrigur@od.nih.gov.

SUPPLEMENTARY INFORMATION: The technology claimed in the aforementioned patent and patent applications relates to methods of treating inflammatory bowel diseases through the administration of antibodies against IL–12. A method for evaluating the effectiveness of the IL–12 antibodies in reducing the inflammatory response is also claimed.

The prospective co-exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective co-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 establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7. This notice serves to modify the previous intent to grant notice published in the **Federal Register**, 62 FR 13162, March 19, 1997.

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 co-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 16, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–7225 Filed 3–22–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Use of Recombinant Cholera Toxin B Subunit to Treat Autoimmune and/or Inflammatory Diseases

AGENCY: National Institutes of Health, Public Health Service, and 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 license to practice the inventions embodied in PCT Patent Application, S/N PCT/US00/30837, entitled, ''Methods of Treating Inflammatory Bowel Disease Using Cholera Toxin B Subunit'' which was filed on November 9, 2000 and claims priority to U.S. Patent Application, S/N 60/165,111, entitled, ''Methods of Treating Inflammatory Bowel Disease Using Cholera Toxin B

Subunit,'' which was filed on November 12, 1999, and corresponding foreign patent applications, to Active Biotech Research AB which is located in Lund, Sweden. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human therapeutics for the treatment of inflammatory bowel disease and/or other human autoimmune or inflammatory diseases.

DATES: Only *written* comments and/or license applications which are received by the National Institutes of Health on or before May 22, 2001 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Richard U. Rodriguez, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 496–7056, X287; Facsimile: (301) 402–0220; and E-mail: RodriguR@od.nih.gov.

SUPPLEMENTARY INFORMATION: The technology claimed in the PCT application relates to methods for treating inflammatory and/or autoimmune diseases through the administration of recombinant cholera toxin B subunit (rCTB). This treatment appears to suppress the production of interferon-gamma and interleukin-12 thus causing apoptosis, or cell death, in a select pool of T-cells. The administration of rCTB may be particularly useful for the treatment of inflammatory bowel disease which would include, but not necessarily be limited to, Crohn's disease and ulcerative colitis.

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 Part 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 establish 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 16, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–7226 Filed 3–22–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), National Toxicology Program (NTP); Request for Data and Nominations of Expert Scientists for an Independent Peer Review Evaluation of In Vitro Estrogen and Androgen Receptor Binding and Transcriptional Activation Assays for Endocrine Disruptor Screening

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is planning an independent Peer Review Panel (hereafter, Panel) evaluation of the validation status of in vitro estrogen receptor (ER) and androgen receptor (AR) binding and transcriptional activation assays. Conclusions and recommendations from the Panel will be considered by federal agencies in selecting and establishing minimum performance criteria for in vitro test methods used to screen chemicals for potential endocrine disrupting effects, including the U.S. Environmental Protection Agency's (EPA) Endocrine Disruptor Screening Program. At this time, NICEATM requests study results and data evaluating the performance and reliability of ER and AR binding and transcriptional activation assays, and other relevant information from the scientific community that should be considered by the Panel. NICEATM also requests nominations of expert scientists for consideration as potential Panel members.

BACKGROUND INFORMATION: In response to public concern that pesticides may interfere with endocrine processes in humans and wildlife, Congress directed EPA, through the 1996 Food Quality Protection Act (FQPA) (Pub. L. 104–170) to develop a screening program for evaluating the potential of pesticides and other chemicals to induce hormone-related health effects. Language in the1996 amendments to the Safe Drinking Water Act (Pub. L. 104–182) added that EPA would use this screening program to evaluate substances found in drinking water sources for endocrine effects if there is widespread human exposure to such substances. Consequently, in 1998, EPA proposed an Endocrine Disruptor Screening Program (EDSP) (**Federal Register**, Vol. 63, No. 248, pp. 71541–71568, December 28, 1998, available at *http://www.epa.gov/fedrgstr/EPA–TOX/1998/December/Day-28/t34298.htm*).

The conceptual framework of the EDSP (*http://www.epa.gov/scipoly/oscpendo/index.htm*) consists of a Tier 1 Screening battery of tests that is designed to identify substances capable of interacting with the endocrine system, and a Tier 2 Testing level that is designed to confirm Tier 1 results and characterize the nature of the endocrine disrupting effects of the substances identified with Tier 1 Screening. Under the mandates of the FQPA, EPA is requiring that each screen and test method proposed for use in the program undergo standardization and scientific validation consistent with the principles of ICCVAM, as described in NIH Publication 97–3981, Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM Report), available at *http://iccvam.niehs.nih.gov/validate.pdf* and the Organization for Economic Co-operation and Development (OECD) (Final Report of the OECD Workshop on Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Test Methods: OECD, 1996, available at *http://www.oecd.org//ehs/test/08e69840.pdf*).

EPA nominated the ER and AR binding assays and ER and AR transcriptional activation assays for review using the ICCVAM evaluation process, and agreed to sponsor the necessary background review document preparation and peer review. ICCVAM subsequently recommended that these methods should undergo independent scientific peer review based on their potential interagency applicability and public health significance. NICEATM, in collaboration with ICCVAM, is therefore convening an independent panel of scientists to assess the validation status of these four different types of in vitro assays. These assays are relevant for screening purposes in the EDSP because they may identify substances that alter natural endocrine processes in the body by binding with estrogen and/or androgen receptors, resulting in either activation or