DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee.

Date: June 19–20, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2149, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 496–3528, *gm12w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13842 Filed 6–2–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Disease; 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 provision 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: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: June 10, 2003.

Time: 9 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, Bethesda, MD 20817.

Contact Person: John R. Lymangrover, PhD, Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301–594–4952.

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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–13845 Filed 6–2–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program (NTP); Notice of Availability of the Report: ''Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Evaluation of In Vitro Test Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays''

Summary

The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of the report entitled, ''ICCVAM Evaluation of In Vitro Test Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays,'' NIH Publication 02–4503. The report contains ICCVAM's recommendations on minimum procedural standards and reference substances for standardization and validation of in vitro estrogen and androgen receptor binding and transcriptional activation assays.

Availability of Report

The report is available electronically (PDF format) on the NICEATM/ICCVAM web site at *http://iccvam.niehs.nih.gov.* A limited number of printed reports and CDs are available. To receive a printed report or CD, please send a request to Dr. William S. Stokes, Director, NICEATM, PO Box 12233, MD EC–17, Research Triangle Park, NC 27709, phone: 919–541–2384, fax: 919–541–0947, or email *niceatm@niehs.nih.gov.* Inquiries about the report or its availability should be sent to Dr. Stokes at the above address.

Background

In April 2000, the EPA asked the ICCVAM to evaluate the validation status of in vitro estrogen receptor (ER) and androgen receptor (AR) binding and transcriptional activation (TA) assays that were proposed as possible components of the EPA Endocrine Disruptor Screening Program (EDSP) Tier 1 screening battery. ICCVAM, which is charged by law (Pub. L. 106–545) to evaluate the scientific validity of new, revised, and alternative test methods proposed for specific regulatory uses, agreed to evaluate these test methods based on their potential interagency applicability and public health significance.

The NICEATM, which administers and provides scientific support for the ICCVAM, subsequently compiled available data and information on in vitro ER and AR binding and TA assays. Four draft Background Review Documents (BRDs) (available at *http://iccvam.niehs.nih.gov/methods/endocrine.htm*) were prepared according to published guidelines for submission of test methods to ICCVAM (ICCVAM 1999). This comprehensive review found that there are no adequately standardized and validated in vitro ER- or AR-based test methods. The NICEATM proposed minimum procedural standards that should be incorporated into standardized protocols for each of the four types of assays. In addition, NICEATM included within each BRD a list of proposed substances that should be used for the validation of in vitro ER and AR binding and TA assays.

In collaboration with the ICCVAM Endocrine Disruptor Working Group (EDWG), NICEATM organized an independent technical evaluation of the four types of in vitro endocrine disruptor test methods on May 20–21, 2002 in Research Triangle Park, NC [**Federal Register**. 66 FR 57: 16278–16279, March 23, 2001 and 67 **Federal Register** 66: 16415–16416, April 5, 2002). This meeting was open to the public with time set aside for public comment.

A 24-member scientific expert panel reviewed the information and recommendations provided in the four draft BRDs and developed its own conclusions and recommendations for each type of test method on the following:

- Specific test methods that should undergo further evaluation in validation studies and their relative priority for evaluation;
- The adequacy of the proposed minimum procedural standards;
- The adequacy of protocols for specific test methods recommended for validation; and
- The adequacy and appropriateness of substances proposed for validation studies.

The expert panel presented its evaluations, conclusions, and recommendations at the meeting. Following the meeting, the expert panel's written evaluations and consensus recommendations were consolidated into an independent report (*http://iccvam.niehs.nih.gov/methods/endocrine.htm*).

In October 2002 (67 FR 204: 64902–64903, October 22, 2002), the NICEATM made available for public comment the expert panels' final report. This report contains the expert panel's evaluations and consensus recommendations for the four types of assays and a revised list of proposed substances for validation of in vitro ER and AR binding and TA test methods. Following review of this report and the public comments, ICCVAM finalized its recommendations and developed recommended minimum procedural standards and the list of proposed substances that should be used to standardize and validate in vitro ER and AR binding and TA assays. The final expert panel report, public comments, and other relevant documents are appended to the ICCVAM report. The ICCVAM report, whose availability is announced in this notice (see above), will be forwarded to Federal agencies for their consideration and information.

The minimum procedural standards and the list of recommended substances for validation should facilitate standardization and validation of in vitro endocrine disruptor assays. Data from validation studies on test methods that incorporate the recommended minimum procedural standards will serve as the basis for developing minimum performance standards for acceptable in vitro ER-or AR-based test methods. The EDSP will use data generated from validated in vitro and in vivo Tier 1 screening test methods to reach weight-of-evidence decisions on whether to conduct large multi-generational in vivo studies. It is also anticipated that data obtained during the validation of the four different types of in vitro ER- and AR-based test methods will help characterize the extent to which individual or batteries of in vitro endocrine disruptor test methods might be used to prioritize chemicals for Tier 1 screening and Tier 2 testing. Finally, implementation of the recommendations in this report is expected to decrease and perhaps eventually eliminate the need to use male and female animals as a source of AR and ER, respectively, for in vitro screening assays.

Test method developers are encouraged to submit in vitro test methods for evaluation by ICCVAM that adhere to the minimum procedural standards outlined in this report and that have undergone validation using the recommended substances. Following adequate validation of in vitro endocrine disruptor test methods, ICCVAM and NICEATM will coordinate their scientific peer review. Formal ICCVAM test recommendations will then be forwarded to Federal agencies as required by the ICCVAM Authorization Act of 2000 (Pub. L. 106–545).

Dated: May 28, 2003.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

[FR Doc. 03–13839 Filed 6–2–03; 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: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Evaluation of the Buprenorphine Waiver: Addiction Physician Survey—New—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT), is evaluating a program that permits office-based physicians to obtain Waivers from the requirements of the Narcotic Addict Treatment Act of 1974 (21 U.S.C. 823 (g)). Under the Drug Addiction Treatment Act of 2000 (21 U.S.C 823 (g)(2)), the Waiver Program permits qualifying physicians to prescribe and dispense buprenorphine, a schedule III narcotic drug recently approved by the FDA for the treatment of opiate addiction. Furthermore, the Drug Abuse Treatment Act specifies that the Secretary of the Department of Health and Human Services make a determination of whether: (1) Treatments provided under the Waiver Program have been effective forms of maintenance treatment and detoxification treatment in clinical settings; (2) the Waiver Program has significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and, (3) the Waiver Program has adverse consequences for the public health. In addition to the objectives above, the Evaluation of the Buprenorphine Waiver Program will examine other related objectives, including: (1) Describing the impact of the Waiver-based treatment on the existing treatment system; (2) providing information useful to guide and refine the processing/monitoring system being developed and maintained by CSAT/DPT; and (3) providing baseline data to inform future research and policy concerning the medicalization and mainstreaming of addiction treatment.

The evaluation by DPT of the Buprenorphine Waiver Program will be accomplished using three survey efforts. The first of these is a mail survey of addiction physicians from the American Society of Addiction Medicine (ASAM) and/or the American Academy of Addiction Psychiatry (AAAP). Some of these specialists will be prescribing and distributing buprenorphine, while others not prescribing buprenorphine may or may not provide referrals or ancillary services to patients receiving buprenorphine treatment. The survey will provide early data about the availability, effectiveness, and public health consequences associated with the Waiver Program. Specifically, the survey will assess early perceptions of