

Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 7, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-23348 Filed 10-18-04; 8:45 am]

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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 Oral, Dental and Craniofacial Sciences Study Section, October 26, 2004, 8:30 a.m., to October 27, 2004, 3 p.m., The River Inn, 924 25th Street, NW., Washington, DC 20037, which was published in the **Federal Register** on October 5, 2004, 69 FR 59602-50603.

The meeting will be held at Comfort Inn—Pentagon, 2480 South Glebe Road, Arlington, VA 22206. The dates and time remain the same. The meeting is closed to the public.

Dated: October 12, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-23344 Filed 10-18-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Genetic Variation and Evolution Study Section, October 14, 2004, 8 a.m., to October 16, 2004, 4 p.m., The River Inn, 924 25th Street, NW., Washington, DC 20037, which was published in the **Federal Register** on September 16, 2004, 69 FR 55830-55832.

The meeting is cancelled due to lack of quorum.

Dated: October 17, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-23349 Filed 10-18-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Renal and Urological Studies Integrated Review Group Cellular and Molecular Biology of the Kidney Study Section.

Date: October 12-13, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Shirley Hilden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7814, Bethesda, MD 20892, (301) 435-1198, hildens@csr.nih.gov.

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 CBSS (01) Cancer Biomarkers.

Date: October 24-26, 2004.

Time: 6:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Mary Bell, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7804, Bethesda, MD 20892, (301) 451-8754, bellmar@csr.nih.gov.

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Gonorrhoea.

Date: October 26, 2004.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Rm 3206, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20982, (301) 435-1149, elzaataf@csr.nih.gov.

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel Clinical CV.

Date: November 3-4, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Russell T. Dowell, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, MSC 7814, Bethesda, MD 20892, (301) 435-1850, dowellr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel SBIR Disease, Health Related Behavior and Education.

Date: November 3, 2004.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Claire E. Gutkin, PhD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7759, Bethesda, MD 20892, (301) 594-3139, gutkincl@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Research Ethics Study Section.

Date: November 3, 2004.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Hyatt Regency, One Metro Center, Bethesda, MD 20814.

Contact Person: Karin F. Helmers, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, (301) 435-1017, helmersk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Muscle.

Date: November 3, 2004.

Time: 9:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Aftab A. Ansari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, (301) 594-6376, ansaria@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Prokaryotic

and Eukaryotic Genetics and Molecular Biology.

Date: November 3–5, 2004.

Time: 7 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mary P. McCormick, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2208, MSC 7890, Bethesda, MD 20892, (301) 435–1047, mccormim@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fetal Basis for Adult Disease.

Date: November 3–4, 2004.

Time: 7 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Ray Bramhall, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046 F, MSC 7892, Bethesda, MD 20892, (910) 458–1871, bramhallr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 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: October 7, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–23350 Filed 10–18–04; 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); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM): Availability of Updated Standardized *In Vitro* Cytotoxicity Test Method Protocols for Estimating Acute Oral Systemic Toxicity; Request for Existing *In Vivo* and *In Vitro* Acute Toxicity Data

Summary: NICEATM announces the availability of two updated standardized *in vitro* cytotoxicity test method protocols to estimate acute oral systemic toxicity in rodents. These two test methods were previously recommended by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for selecting starting doses for *in vivo* acute oral systemic toxicity tests (**Federal**

Register Vol. 66, No. 189, pages 49686–49687, September 28, 2001). This approach can reduce the number of animals required for acute oral toxicity testing. NICEATM also requests the submission of existing and future data on chemicals and products tested for both acute oral systemic toxicity and *in vitro* cytotoxicity using the standardized test method protocols mentioned in this notice. These data will be used to further evaluate the usefulness and limitations of cytotoxicity methods for estimating *in vivo* acute oral toxicity. The data will also be used to establish a database to support the investigation of other test methods necessary to improve the accuracy of *in vitro* assessments of acute systemic toxicity.

Availability of Standardized Test Method Protocols for Estimating Starting Doses for *In Vivo* Acute Oral Toxicity Tests

Updated standardized protocols for two neutral red uptake assays using either BALB/c 3T3 cells or normal human keratinocytes are now available at: <http://iccvam.niehs.nih.gov/methods/invitro.htm>. These test method protocols have been improved to maximize *intra-* and *inter-laboratory* reproducibility and are currently being used for the final phase of a joint NICEATM-European Center for the Validation of Alternative Methods (ECVAM) validation study. NICEATM recommends that these updated test method protocols be used in place of standard operating procedures previously recommended by ICCVAM for two cytotoxicity test methods to estimate starting doses for *in vivo* acute oral toxicity tests (ICCVAM, 2001b).

Submission of Chemical and Protocol Information/Test Data

In vivo and *in vitro* acute toxicity testing data for chemicals or products should be sent by mail, fax or e-mail to NICEATM [Dr. William S. Stokes, Director, NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) iccvam@niehs.nih.gov]. Data will be accepted at any time. Data submitted within the next 9 months will be considered during an evaluation of the validation status of the two cytotoxicity methods anticipated in late 2005. Chemical and protocol information/test data submitted in response to this notice may be incorporated in future NICEATM and ICCVAM reports and publications as appropriate.

When submitting chemical and protocol information/test data, 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 study notebooks and/or study reports, if available. Raw data and analyses available in electronic format may also be submitted. 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* basal cytotoxicity test protocol used
- *In vitro* cytotoxicity test results
- *In vivo* acute oral toxicity test protocol used
- Individual animal responses at each observation time (if available)
- The extent to which the study complied with national or international Good Laboratory Practice (GLP) guidelines
- Date and testing organization

Those persons submitting data on chemicals tested for *in vitro* basal cytotoxicity are referred to the standard test-reporting template recommended for the High Production Volume (HPV) program at <http://www.epa.gov/chemrtk/toxprtw.htm> or at <http://iccvam.niehs.nih.gov/methods/invitro.htm>. *In vivo* data for the same chemicals should be reported as recommended in the test reporting section of the current Environmental Protection Agency (EPA) guideline for acute oral toxicity (EPA, 2002).

Submitted data will be used to further evaluate the usefulness and limitations of *in vitro* cytotoxicity data for estimating acute oral toxicity, and will be included in a database to support the investigation of other test methods necessary to improve the accuracy of *in vitro* assessments of acute systemic toxicity.

History

In September 2001, the ICCVAM recommended that *in vitro* cytotoxicity test methods be considered as a tool for estimating starting doses for *in vivo* acute systemic toxicity testing studies (**Federal Register** Vol. 66, No. 189, pages 49686–49687, September 28, 2001.) The recommendations were based on the Report of the International Workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity (ICCVAM, 2001a). The Guidance Document on Using *In Vitro* Data to Estimate *In Vivo* Starting Doses for Acute Toxicity (ICCVAM, 2001b) was