

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892. (301) 435-0903. [saadisoh@csr.nih.gov](mailto:saadisoh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Health of the Population SBIR Study Section Panel.

*Date:* November 2-3, 2006.

*Time:* 8:30 a.m. to 3 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:* 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](mailto:helmersk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Small Business: Non-HIV Anti-Infective Therapeutics.

*Date:* November 2, 2006.

*Time:* 9 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

*Contact Person:* Rossana Berti, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3191, MSC 7846, Bethesda, MD 20892. 301-402-6411. [bertiros@csr.nih.gov](mailto:bertiros@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, RIBT Member Conflicts.

*Date:* November 2, 2006.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* George M. Barnas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7817, Bethesda, MD 20892. 301-435-0696. [barnasg@csr.nih.gov](mailto:barnasg@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Neural Control of Cardiovascular Function.

*Date:* November 2, 2006.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802 Bethesda, MD 20892. (301) 435-1210. [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Technology Development.

*Date:* November 2, 2006.

*Time:* 12 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Sally Ann Amero, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7849, Bethesda, MD 20892. 301-435-1159. [ameros@csr.nih.gov](mailto:ameros@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, GENHAT Collaborative.

*Date:* November 2, 2006.

*Time:* 12:30 p.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Churchill Hotel, 1914 Connecticut Ave., NW., Washington, DC 20009.

*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](mailto:dowellr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Endocrinology, Metabolism, Nutrition and Reproductive Special Emphasis Panel SBIR.

*Date:* November 3, 2006.

*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:* Krish Krishnan, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892. 301-435-1041. [krishnak@csr.nih.gov](mailto:krishnak@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Research on Ethical Issues in Human Studies.

*Date:* November 3, 2006.

*Time:* 9 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

*Contact Person:* Stephen H. Krosnick, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3028A, MSC 7770, Bethesda, MD 20892. 301-435-1712. [krosnics@csr.nih.gov](mailto:krosnics@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Globin Gene Regulation.

*Date:* November 3, 2006.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Robert T. Su, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892. 301-435-1195. [sur@csr.nih.gov](mailto:sur@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Metal Ions and Kinases.

*Date:* November 3, 2006.

*Time:* 12 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Alessandra M. Bini, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892. 301-435-1024. [binia@csr.nih.gov](mailto:binia@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 5, 2006.

**Linda Payne,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-8698 Filed 10-13-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Availability of the Draft Expert Panel Report on Hydroxyurea and Request for Public Comment on the Draft Report; Announcement of the Hydroxyurea Expert Panel Meeting**

**AGENCY:** National Institute for Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

**ACTION:** Announcement of a meeting and request for public comment.

**SUMMARY:** The CERHR announces the availability of the draft expert panel report for hydroxyurea on November 1, 2006, from the CERHR Web site (<http://cerhr.niehs.nih.gov>) or in printed text from the CERHR (see **FOR FURTHER INFORMATION CONTACT** below). The CERHR invites the submission of public comments on sections 1-4 of the draft expert panel report (see **SUPPLEMENTARY INFORMATION** below). The expert panel will meet on January 24-26, 2007, at the Radisson Hotel Old Town in Alexandria, VA, to review and revise the draft expert panel report and reach conclusions regarding whether exposure to hydroxyurea is a hazard to human development or reproduction. The expert panel will also identify data gaps and research needs. CERHR expert panel meetings are open to the public with time scheduled for oral public comment. Attendance is limited only by

the available meeting room space. Following the expert panel meeting and completion of the expert panel report, the CERHR will post the final report on its Web site and solicit public comment on it through a **Federal Register** notice.

**DATES:** The expert panel meeting for hydroxyurea will be held on January 24–26, 2007. Sections 1–4 of the draft expert panel report will be available for public comment on November 1, 2006. Written public comments on the draft report must be received by December 15, 2006. Time is set-aside at the expert panel meeting on January 24, 2007 for oral public comments. Individuals wishing to make oral public comments are asked to contact Dr. Michael D. Shelby, CERHR Director, by January 17, 2007, and if possible, send a copy of the statement or talking points at that time. Persons needing special assistance in order to attend are asked to contact Dr. Shelby at least 7 business days prior to the meeting.

**ADDRESSES:** The expert panel meeting on hydroxyurea will be held at the Radisson Hotel Old Town 901 N. Fairfax Street Alexandria, VA 22314–1501 (telephone: 703–683–6000, facsimile: 703–683–7597). Comments on the draft expert panel report should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), (919) 316–4511 (fax), or [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov) (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

**FOR FURTHER INFORMATION CONTACT:** Dr. Michael D. Shelby, CERHR Director, 919–541–3455, [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

*Hydroxyurea* (CAS RN: 127–07–1) is used in the treatment of cancer, sickle cell disease, and thalassemia. It is the only treatment for sickle cell disease used in children aside from blood transfusion. Hydroxyurea may be used in the treatment of children and adults with sickle cell disease for an extended period of time or for repeated cycles of therapy. Treatment with hydroxyurea may be associated with cytotoxic and myelosuppressive effects and hydroxyurea is mutagenic. Hydroxyurea is FDA-approved for reducing the frequency of painful crises and the need for blood transfusions in adults with sickle cell anemia who experience recurrent moderate to severe painful crises. CERHR selected this chemical for evaluation because of (1) increasing use in the treatment of sickle cell disease in children and adults, (2) knowledge that

it inhibits DNA synthesis and is cytotoxic, and (3) published evidence of reproductive and developmental toxicity in rodents.

At the expert panel meeting, the expert panel will review and revise the draft expert panel report and reach conclusions regarding whether exposure to hydroxyurea is a hazard to human reproduction or development. Each draft expert panel report has the following sections:

- 1.0 Chemistry, Use, and Human Exposure.
- 2.0 General Toxicological and Biological Effects.
- 3.0 Developmental Toxicity Data.
- 4.0 Reproductive Toxicity Data.
- 5.0 Summary, Conclusions, and Critical Data Needs (to be prepared at expert panel meeting).

##### **Request for Comments**

The CERHR invites written public comments on sections 1–4 of the draft expert panel report on hydroxyurea. Any comments received will be posted on the CERHR Web site prior to the meeting and distributed to the expert panel and CERHR staff for their consideration in revising the draft report and preparing for the expert panel meeting. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Shelby (*see ADDRESSES* above) for receipt by December 15, 2006.

Time is set-aside on January 24, 2007, for the presentation of oral public comments at the expert panel meeting. Seven minutes will be available for each speaker (one speaker per organization). When registering to comment orally, please provide your name, affiliation, mailing address, telephone and facsimile numbers, e-mail and sponsoring organization (if any). If possible, send a copy of the statement or talking points to Dr. Shelby by January 17. This statement will be provided to the expert panel to assist them in identifying issues for discussion and will be noted in the meeting record. Registration for presentation of oral comments will also be available at the meeting on January 24, 2007, from 7:30–8:30 a.m. Persons registering at the meeting are asked to bring 20 copies of their statement or talking points for distribution to the expert panel and for the record.

##### **Preliminary Agenda**

The meeting begins each day at 8:30 a.m. On January 24 and 25, it is anticipated that a lunch break will occur

from noon–1 p.m. and the meeting will adjourn at 5–6 p.m. The meeting is expected to adjourn by noon on January 26; however, adjournment may occur earlier or later depending upon the time needed by the expert panel to complete its work. Anticipated agenda topics for each day are listed below.

##### *January 24, 2007*

- Opening remarks.
- Oral public comments (7 minutes per speaker; one representative per group).
- Review of sections 1–4 of the draft expert panel report on hydroxyurea.
- Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs.

##### *January 25, 2007*

- Discussion of Section 5.0 Summary, Conclusions, and Critical Data Needs.
- Preparation of draft summaries and conclusion statements.

##### *January 26, 2007*

- Presentation, discussion of, and agreement on summaries, conclusions, and data needs.
- Closing comments.

##### **Expert Panel Roster**

The CERHR expert panel is composed of independent scientists selected for their scientific expertise in reproductive and/or developmental toxicology and other areas of science relevant for these evaluations.

Erica Liebelt, M.D. (Chair), University of Alabama, Birmingham, AL.  
 Sophie Balk, M.D., Albert Einstein College of Medicine, New York, NY.  
 Will Faber, PhD, Consultant, Victor, NY.  
 Jeffrey Fisher, PhD, University of Georgia, Athens, GA.  
 Claude Hughes, Jr., M.D., PhD, Quintiles, Inc., Research Triangle Park, NC.  
 Sophie Lanzkron, M.D., Johns Hopkins University, Baltimore, MD.  
 Kerry Lewis, M.D., Howard University, Washington, DC.  
 Harihara Mehendale, PhD, University of Louisiana, Monroe, LA.  
 Marvin Meistrich, PhD, University of Texas, Houston, TX.  
 John Rogers, PhD, U.S. Environmental Protection Agency, Research Triangle Park, NC.  
 Aziza Shad, M.D., Georgetown University, Washington, DC.  
 Richard Skalko, PhD, East Tennessee State University, Johnson City, TN.  
 Edward Stanek III, PhD, University of Massachusetts, Amherst, MA.

##### **Background Information on the CERHR**

The NTP established the NTP CERHR in June 1998 [**Federal Register**,

December 14, 1998 [Volume 63, Number 239, page 68782]). The CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

The CERHR invites the nomination of agents for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (see **FOR FURTHER INFORMATION CONTACT** above). The CERHR selects chemicals for evaluation based upon several factors including production volume, potential for human exposure from use and occurrence in the environment, extent of public concern, and extent of data from reproductive and developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** on July 16, 2001 (Volume 66, Number 136, pages 37047–37048) and is available on the CERHR Web site under “About CERHR” or in printed copy from the CERHR.

Dated: October 5, 2006.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

[FR Doc. E6–17137 Filed 10–13–06; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Notice of Availability of the NICEATM Pre-Screen Evaluation of a Cell Proliferation Assay To Detect Estrogenic Activity: Request for Comments and Nominations of Other *In Vitro* Endocrine Disruptor Test Methods

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

**ACTION:** Report availability and request for comments and nominations.

**SUMMARY:** In January 2006, the Interagency Coordinating Committee on Alternative Methods (ICCVAM) received

a test method nomination for the validation of a cell-based estrogen receptor (ER) transcriptional activation (TA) test method from CertiChem, Inc. CertiChem, Inc. submitted a background review document (BRD) containing information on historical development of the test method, the rationale for the test method, and supporting materials. In accordance with the ICCVAM nomination process, NICEATM conducted a pre-screen evaluation of the BRD to determine the extent that it addressed ICCVAM prioritization criteria, submission guidelines, and recommendations for standardization and validation of *in vitro* endocrine disruptor test methods. NICEATM also reviewed the performance of the test method based on pre-validation data to determine if it warranted consideration for further validation. ICCVAM requests public comments on the pre-screen evaluation titled, “Pre-Screen Evaluation of the CertiChem, Inc. *In Vitro* Endocrine Disruptor Assay (Robotic MCF–7 Cell Proliferation Assay of Estrogenic Activity.)” The pre-screen evaluation is available with supporting documents at (<http://iccvam.niehs.nih.gov/methods/endocrine.htm>). ICCVAM also invites public comments on whether this test method should be considered for additional validation studies. In addition, ICCVAM again invites the nomination of other *in vitro* ER and androgen receptor (AR) binding and TA test methods for which there are standardized test method protocols, pre-validation data, and proposed validation study designs.

**DATES:** Comments and nominations should be received by November 30, 2006.

**ADDRESSES:** Correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

In May 2003, ICCVAM published the report, “ICCVAM Evaluation of *In Vitro* Test Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays (NIH Publication No. 03–4503; available: <http://iccvam.niehs.nih.gov/methods/endocrine.htm>). The report recommends minimum procedural standards that should be incorporated in standardized test method protocols and minimum lists of chemicals that should be used

for validation studies. A request was made for nominations of validation studies for *in vitro* ER and AR binding and TA test methods based on these recommendations and for which there are standardized test method protocols, pre-validation data, and proposed validation study designs (69 FR 21564). ICCVAM subsequently received a nomination from CertiChem, Inc. for the validation of a cell-based ER TA method that evaluates the estrogenic activity of substances by measuring whether and to what extent a substance induces cell proliferation via ER-dependent pathways. In support of this nomination, ICCVAM received a BRD containing information on the test method’s historical development, its rationale, its protocol, and other supporting materials. In accordance with the ICCVAM nomination process, NICEATM conducted a pre-screen evaluation of the BRD to determine the extent that it addressed ICCVAM prioritization criteria, submission guidelines, and recommendations for standardization and validation of *in vitro* endocrine disruptor test methods. NICEATM also reviewed the performance of the proposed test method based on pre-validation data to determine if it warranted consideration for further validation. The BRD was reviewed for completeness and to identify aspects or omissions that could impede further review. The criteria considered in evaluating information provided in the BRD are:

- The extent to which the BRD addresses ICCVAM prioritization criteria.
- The extent to which the BRD provides the information requested in the *ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods* (NIH Pub. No. 03–4508, available at <http://iccvam.niehs.nih.gov>).
- The extent to which the proposed test method adheres to the recommendations of the *ICCVAM Evaluation of In Vitro Test Methods for Detecting Potential Endocrine Disruptors* (NIH Pub. No. 03–4503, available at <http://iccvam.niehs.nih.gov/methods/endocrine.htm>), especially those regarding essential test method components and recommended validation substances.
- The extent to which the proposed test method shows adequate performance (reliability and accuracy) during pre-validation to warrant consideration for validation studies.

Based on the pre-screen evaluation, ICCVAM made a draft recommendation that this test method be considered as a high priority for validation studies to