

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]

BILLING CODE 4140–01–M

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

also made available at that time. The guidance document provided standard operating procedures for two cytotoxicity test methods and instructions for using these assays to estimate starting doses for in vivo testing.

Federal agency responses to the ICCVAM test method recommendations were announced on March 10, 2004 (**Federal Register** Vol. 69, No. 47, pages 11448–11449). Federal agencies agreed to encourage, to the extent applicable, the use of in vitro tests for determining starting doses for acute systemic toxicity testing. Furthermore, EPA specifically encouraged those participating in the HPV Challenge Program to consider using the recommended in vitro tests as a supplemental component in conducting any new in vivo acute oral toxicity studies for the program (<http://www.epa.gov/chemrtk/toxprow.htm>).

A NICEATM–ECVAM validation study was initiated in 2002 to evaluate the usefulness of the two neutral red uptake cytotoxicity assays currently available for predicting starting doses for in vivo acute oral toxicity tests. During the pre-validation phases of the study, the test method protocols were further standardized and revised to improve their intra- and inter-laboratory reproducibility. NICEATM recommends using the revised test method protocols rather than the standard operating procedures outlined in the guidance document (ICCVAM, 2001b.) The guidance document should be consulted for the procedure for calculating starting doses using in vitro cytotoxicity data.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from fifteen Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM promotes the development, validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess the safety or hazards of chemicals and products, and test methods that refine, reduce and replace animal use. The ICCVAM Authorization Act of 2000 (available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) established ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific support for ICCVAM and ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the

needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: <http://iccvam.niehs.nih.gov/>.

References

EPA. 2002. Health Effects Test Guidelines, OPPTS 870.1100, Acute Oral Toxicity, EPA 712–C–02–190. Available at: http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-1100.pdf.

ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods). 2001a. Report of the international workshop on in vitro methods for assessing acute systemic toxicity. NIH Publication 01–4499. Research Triangle Park, NC: National Institute for Environmental Health Sciences. Available at: <http://iccvam.niehs.nih.gov/>.

ICCVAM. 2001b. Guidance document on using in vitro data to estimate in vivo starting doses for acute toxicity. NIH Publication 01–4500. Research Triangle Park, NC: National Institute for Environmental Health Sciences. Available at: <http://iccvam.niehs.nih.gov/>.

Dated: October 6, 2004.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–23335 Filed 10–18–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD17–04–002]

Cook Inlet Regional Citizen's Advisory Committee; Charter Renewal

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The Coast Guard has recertified the Cook Inlet Regional Citizen's Advisory Council for the period covering September 1, 2004 through August 31, 2005. Under the Oil Terminal and Oil Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Cook Inlet, Alaska. This advisory group monitors the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the statute.

DATES: The Cook Inlet Regional Citizen's Advisory Council is certified through August 31, 2005.

ADDRESSES: You may request a copy of the recertification letter by writing to Commander, Seventeenth Coast Guard District (mor), P.O. Box 25517, Juneau, AK 99802–5517.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Andrew Vanskike, Seventeenth Coast Guard District (mor), 907–463–2818.

SUPPLEMENTARY INFORMATION:

Background And Purpose

On September 1, 2004, the Coast Guard recertified the Cook Inlet Regional Citizen's Advisory Council (CIRCAC) through August 31, 2005. Under the Oil Terminal and Oil Tanker Environmental Oversight Act of 1990 (33 U.S.C. 2732), the Coast Guard may certify, on an annual basis, an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Cook Inlet, Alaska. This advisory group monitors the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by Congress, 33 U.S.C. 2732 (b).

On September 16, 2002, the Coast Guard published a notice of policy on revised recertification procedures for alternative voluntary advisory groups in lieu of councils at Prince William Sound and Cook Inlet, AK (67 FR 58440, 58441). This revised policy indicated that applicants seeking recertification in 2003 and 2004 need only submit a streamlined application and public comments would not be solicited prior to recertification.

Dated: September 24, 2004.

James C. Olson,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 04–23370 Filed 10–18–04; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Notice of Adjustment of Countywide Per Capita Impact Indicator

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: FEMA gives notice that the countywide per capita impact indicator under the Public Assistance program for disasters declared on or after October 1, 2004 will be increased.

DATES: Effective October 1, 2004 and applies to major disasters declared on or after October 1, 2004.

FOR FURTHER INFORMATION CONTACT: James A. Walke, Recovery Division, Federal Emergency Management