Appendix O

Federal Register Notices

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committee (NMQAAC). Concurrently, nomination materials for prospective candidates should be sent to FDA by April 21, 2005. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to the contact person listed in the **FOR FURTHER INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0450, ext. 114.

SUPPLEMENTARY INFORMATION: The Mammography Quality Standards Reauthorization Act of 2004 (Public Law 108–365) requires the addition of at least two industry representatives with expertise in mammography equipment to the National Mammography Quality Assurance Advisory Committee.

I. Functions of NMQAAC

The functions of the NMQAAC are to advise FDA on: (1) Developing appropriate quality standards and regulations for mammography facilities, (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program, (3) developing regulations with respect to sanctions, (4) developing procedures for monitoring compliance with standards, (5) establishing a mechanism to investigate consumer complaints, (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities, (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas, (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999, and (9) determining the costs and benefits of compliance with these requirements.

II. Selection Procedure

Any organization representing the mammography device industry wishing to participate in the selection of a nonvoting member to represent industry should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Persons who nominate themselves as industry representatives will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing the a particular committee. If no individual is selected within the 60 days, the Commissioner of Food and Drugs (the Commissioner) may select the nonvoting member to represent industry interests.

III. Qualifications

Persons nominated for membership on the committee as an industry representative must meet the following criteria:(1) Demonstrate expertise in mammography equipment and (2) be able to discuss equipment specifications and quality control procedures affecting mammography equipment. The industry representative must be able to represent the industry perspective on issues and actions before the advisory committee; serve as liaison between the committee and interested industry parties; and facilitate dialogue with the advisory committee on mammography equipment issues.

IV. Application Procedure

Individuals may nominate themselves, or an organization representing the mammography device industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the committee of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations that have expressed interest in participating in the selection process for the committee.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: March 14, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–5551 Filed 3–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program; National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Nominations for an Independent Peer Review Panel To Evaluate In Vitro Testing Methods for Estimating Acute Oral Systemic Toxicity and Request for In Vivo and In Vitro Data

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

ACTION: Request for nominations for an independent peer review panel and request for *in vivo* and *in vitro* data.

SUMMARY: The NTP Interagency Center for Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is planning to convene an independent peer review panel (hereafter, Panel) to evaluate the validation status of two *in vitro* cytotoxicity assays for estimating *in vivo* acute oral toxicity. The Panel will evaluate the usefulness, limitations, accuracy, and reliability of these test methods for their intended purpose. NICEATM requests nominations of expert scientists for consideration as potential Panel members. ICCVAM will consider the conclusions and recommendations from the Panel in developing test method recommendations and performance standards for these test methods. Data from standard *in vivo* acute oral toxicity testing and *in vitro* cytotoxicity testing also is requested.

DATES: Nominations and data should be received by noon on May 6, 2005.

ADDRESSES: Nominations and data should be sent by mail, fax, or e-mail to Dr. William S. Stokes, Director of NICEATM, at NICEATM, 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.* Courier address: NICEATM, 79 T.W. Alexander Drive,

Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: NICEATM, 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.*

SUPPLEMENTARY INFORMATION:

Background

NICEATM and the European Committee on the Validation of Alternative Methods (ECVAM) conducted a collaborative validation study to independently evaluate the usefulness of two *in vitro* basal cytotoxicity assays proposed for estimating *in vivo* rat acute oral toxicity. Neutral red uptake assays using both a mouse cell line (*i.e.,* BALB/c 3T3 fibroblasts) and a primary human cell type (*i.e.,* normal human epithelial keratinocytes) were evaluated in a multi-laboratory validation study. Cytotoxicity results are proposed for use in predicting starting doses for *in vivo* acute oral lethality assays, which may reduce the number of animals required for such determinations.

NICEATM is preparing Background Review Documents on the two *in vitro* test methods that will contain comprehensive summaries of available data, an analysis of the accuracy and reliability of standardized test method protocols, and related information characterizing the current validation status of these assays. Once completed, the Background Review Documents will be provided to the Panel and made available to the public. Meeting information, including date and location, and public availability of the Background Review Documents will be announced in a future **Federal Register** notice and posted on the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov*).

Request for the Nomination of Scientists for the Peer Review Panel

NICEATM invites nominations of scientists with relevant knowledge and experience to serve on the Panel. Areas of relevant expertise include, but are not limited to: physiology and pharmacology, acute systemic toxicity testing in animals, evaluation and treatment of acute toxicity in humans, development and use of *in vitro* methodologies, biostatistical data analysis, knowledge of chemical data sets useful for validation of acute toxicity studies, and hazard classification of chemicals and products. Each nomination should include the person's name, affiliation, contact information (*i.e.* mailing address, e-mail address, telephone and fax numbers), and a brief summary of relevant experience and qualifications. Nominations should be sent to NICEATM by mail, fax, or e-mail within 45 days of the publication of this notice. Correspondence should be directed to Dr. William Stokes, Director, NICEATM, at the address given above.

Request for Data

NICEATM invites the submission of data from standard *in vivo* acute oral toxicity testing and *in vitro* cytotoxicity testing. Two previous requests for existing *in vivo* and *in vitro* acute toxicity data have been made (**Federal Register,** Vol. 69, No. 201, pp. 61504–5, October 19, 2004 and Vol. 65, No. 115, pp. 37400–3, June 14, 2000). *In vivo* and *in vitro* acute toxicity testing data for chemicals or products should be sent to NICEATM by mail, fax, or e-mail to the address given above. Data submitted by the deadline listed in this notice will be considered during an evaluation of the validation status of the two cytotoxicity methods, anticipated in late 2005; however, data will be accepted at any time. 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 class.
- 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/toxprtow.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.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for 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.*

Dated: March 11, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–5564 Filed 3–21–05; 8:45 am]

BILLING CODE 4140–01–P

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, *bramhalr@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/toxprtow.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/toxprtow.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

Natives (AI/AN) tribal governments to all available programs in the Department of Health and Human Services (HHS), and coordinate the tribal consultation activities associated with formulation of the IHS annual budget request. The application is for a five year project which will commence with an initial award on March 15, 2004. The initial budget period will be awarded at $227,00.00 and the entire project is expected to be awarded at $1,135,000.00.

The award is issued under the authority of the Public Health Service Act, section 301(a) and is included under the Catalog of Federal Domestic Assistance number 93.933. The specific objectives of the project are to:

1. Provide ongoing technical advice and consultation as the national Indian organization that is representative of all tribal governments in the area of health care policy analysis and program development.

2. Assure that health care advocacy is based on tribal input through a broad-based consumer network involving the Area Indian Health Boards or Health Board Representatives from each of the 12 IHS Areas.

3. Establish relationships with other national Indian organizations, with professional groups and with Federal, State and local entities to serve as advocates for AI/AN health programs. As a recipient of a grant/cooperative agreement, the NIHB is prohibited from conducting lobbying activities using Federal funding.

4. Improve and expand access for AI/AN tribal governments to all available programs in the HHS.

5. Publish, at least three times a year, a newsletter featuring articles on health promotion/disease prevention activities and models of best or improving practices, health policy and funding information relevant to AI/AN, *etc.*

6. Disseminate timely health care information to tribal governments, AI/AN Health Boards, other national Indian organizations, professional groups, Federal, State, and local entities.

7. Coordinate the tribal consultation activities associated with formulation of the IHS annual budget request.

Justification for Single Source: This project has been awarded on a non-competitive single source basis. NIHB is the only national AI/AN organization with health expertise that represents the interest of all federally recognized tribes.

Use of Cooperative Agreement: A non-competitive single source Cooperative Agreement Award will involve:

1. IHS staff will review articles concerning the Agency for accuracy and may, as requested by the NIHB, provide articles.

2. IHS staff will have aproval over the hiring of key personnel as defined by regulation or provision in the cooperative agreement.

3. IHS will provide technical assistance to the NIHB as requested and attend and participate in all NIHB Board meetings.

FOR FURTHER INFORAMTION CONTACT: Douglas Black, Director, Office of Tribal Programs, Office of the Director, Indian Health Service, 801 Thompson Avenue, Reyes Building, Suite 220, Rockville, Maryland 20852, telephone (301) 443–1104. For grants information, contact Sylvia Tyan, Grants Management Specialist, Division of Acquisition and Grants Management Branch, 1200 Twinbrook Parkway, Room 450A, Rockville, Maryland 20852, telephone (301) 443–5204.

Dated: March 1, 2004.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 04–5305 Filed 3–9–04; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Meeting

The Office of the Director, National Institutes of Health (NIH), announces a meeting of the NIH Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the director, NIH. The meeting is scheduled for March 12–13, 2004. The meeting will be held at the NIH, 9000 Rockville Pike, Bethesda, Maryland, Building 31C, Conference Room 6. Attendance will be limited to space available. In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to shop a photo I.D. and sign in at the security desk upon entering the building.

On March 12, the Panel will meet in closed, Executive Session, from 8:30–10 a.m., and in public session, from 10 a.m.–6:15 p.m. On March 13, the Panel will meet in closed, Executive Session, from 8:30 a.m.–2 p.m. The agenda will be posted on the NIH Web site *(http://www.nih.gov)* prior to the meeting.

During the public session, time will be set aside for oral presentations by the public. Any person wishing to take a presentation should notify Charlene French, Office of Science Policy, National Institutes of Health, Building 1, Room 103, Bethesda, Maryland 20892, telephone (301) 496–2122 by March 11, 2004 or by e-mail: *blueribbonpanel@mail.nih.gov.*

Oral comments will be limited to 5 minutes. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotment may also be limited by the number of presentations. The opportunity to speak will be based on a first come first served basis. All requests to present oral comments should include the name, addresses, telephone number, and business or professional affiliation of the interested party, and should indicate the areas of interest or issue to be addressed. Please provide, if possible, an electronic copy of your comments.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement during the time set aside for public comment, if time permits and at the discretion of the co-chairs.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Charlene French at the address listed earlier in this notice in advance of the meeting.

Dated: March 5, 2004.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–5504 Filed 3–8–04; 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); Notice of the Availability of Agency Responses to ICCVAM Test Recommendations for the Revised Up-and-Down Procedure for Determining Acute Oral Toxicity and In Vitro Methods for Assessing Acute Systemic Toxicity

Summary

The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of Federal agency responses to Interagency Coordinating Committee on the Validation of Alternative Methods

(ICCVAM) test recommendations for: (1) The revised Up-and-Down Procedure (UDP) for determining acute oral toxicity and (2) *in vitro* methods for assessing acute systemic toxicity. Pursuant to sections 3 of the ICCVAM Authorization Act of 2000 [Pub. L. 106–545 (42 U.S.C. 285l–4)], ICCVAM is required to make final ICCVAM test recommendations and the responses from agencies regarding such recommendations available to the public.

Availability of Agency Responses

The agency responses to the ICCVAM test recommendations and other current information relevant to these test recommendations are available electronically (PDF and HTML formats) on the NICEATM/ICCVAM Web site at *http://iccvam.niehs.nih.gov.* Hard copy versions of these responses can be requested by contacting NICEATM at P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709 (mail), 919–541–2384 (telephone), 919–541–0947 (fax), or *niceatm@niehs.nih.gov.*

In summary, the Federal agencies agreed that the UDP had been adequately validated as a replacement for the conventional LD50 test and indicated to the extent applicable, that they will encourage the use of *in vitro* tests for determining starting doses for acute systemic toxicity testing.

ICCVAM Recommmendations

NICEATM announced availability of the ICCVAM recommendations for the UDP on February 7, 2002 (**Federal Register** Vol. 67, No. 26, pages 5842–5844). ICCVAM recommends based upon the report, *The Revised Up-and-Down Procedure: A Test Method for Determining the Acute Oral Toxicity of Chemicals; Results of an Independent Peer Review Evaluation Organized by the ICCVAM and NICEATM,* NIH Publication No. 02–4501, that the UDP be used instead of the conventional LD50 test to determine the acute oral toxicity hazard of chemicals for hazard classification and labeling purposes.

NICEATM announced availability of the ICCVAM recommendations for the *in vitro* methods for assessing acute systemic toxicity on September 28, 2001 (**Federal Register** Vol. 66, No. 189, pages 49686–49687). ICCVAM recommends based upon the reports, *Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity,* NIH Publication No. 01–4499, and the *Guidance Document on Using In Vitro Data to Estimate In Vivo Starting Doses for Acute Toxicity,* NIH Publication No. 01–4500, that the *in vitro* methods be considered as a tool for estimating starting doses for animal tests of acute systemic toxicity.

Background Information on ICCVAM and NICEATM

The NIEHS established the ICCVAM in 1997 to coordinate the interagency technical review of new, revised, and alternative test methods of interagency interest, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM was established as a permanent interagency committee of the NIEHS under the NICEATM on December 19, 2000, by the ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.pdf*). The Committee is composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. ICCVAM promotes the scientific validation and regulatory acceptance of toxicological test methods that will improve agencies' ability to accurately assess the safety or hazards of chemicals and various types of products, while refining (less pain and distress), reducing, and replacing animal use wherever possible. NICEATM administers the ICCVAM and provides scientific and operational 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.*

Dated: March 2, 2004.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–5321 Filed 3–9–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2000–7848]

Inland Tank Barge Certificates of Inspection; Administrative Changes

AGENCY: Coast Guard, DHS.

ACTION: Notice of results.

SUMMARY: The Coast Guard commissioned a one-year tank barge Certificate of Inspection (COI) pilot program to test administrative changes to inland tank barge COIs. Under the old Marine Safety Information System, a regulatory change would have been required had any changes been made to the COIs. Use of the new Marine Information for Safety and Law Enforcement information system allows easy access to the COIs; therefore no change in the regulations is needed.

DATES: No further actions are planned.

FOR FURTHER INFORMATION CONTACT: For questions on this Notice, contact Commander Robert Hennessy, U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001, telephone: 202–267–0103, facsimile: 202–267–4570, e-mail: *RHennessy@comdt.uscg.mil* or Lieutenant Raymond Lechner, U.S. Coast Guard Marine Safety Center, 400 7th Street, SW., Washington, DC 20590, telephone: 202–366–6462, e-mail: *RLechner@msc.uscg.mil.*

SUPPLEMENTARY INFORMATION: A pilot program was initiated to evaluate a Chemical Transportation Advisory Committee (CTAC) recommendation. The pilot program assessed the benefits of shifting the vessel cargo authority and conditions of carriage information from one required document (the vessel's Certificate of Inspection (COI)) to another required document (the vessel's cargo transfer procedures). Background information about the pilot program conducted by the Marine Safety Office, New Orleans, LA, in cooperation with the Marine Safety Center, American Commercial Barge Lines, and the Petroleum Services Corporation, can be found in the August 31, 2000, **Federal Register** Notice (65 FR 53071).

Since the pilot program was initiated, the Coast Guard now has the Marine Information for Safety and Law Enforcement (MISLE) information system in use. MISLE allows for a different presentation of cargo information than the old Marine Safety Information System. A Certificate of Inspection for inland tank barges and a newly developed Cargo Authority Attachment are now easily accessible from the MISLE; therefore, no changes in the regulations are required. Additional information can be found on the Marine Safety Center's Web site: *http://www.uscg.mil/hq/msc/T2.misle.htm* under ''T2: Tank Vessel Cargo and Vapor Control Authority Under MISLE.''

Dated: February 27, 2004.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security and Environmental Protection.

[FR Doc. 04–5300 Filed 3–9–04; 8:45 am]

BILLING CODE 4910–15–P

valid for use as replacements for the animal test and were ready to be considered for regulatory acceptance (Balls and Corcelle, 1998; Balls and Hellsten, 2000). The European Scientific Committee for Cosmetic Products and Non-food Products (SCCNFP) evaluated the EPISKIN™ and Rat Skin TER and concluded that they were applicable for the safety evaluation of cosmetic ingredients or mixtures of ingredients (Anon., 1999). The European Commission subsequently adopted EpiDerm™, EPISKIN™, and Rat Skin TER (Anon., 2000).

Proposed ICCVAM Recommendations

ICCVAM proposes that these assays can be used to assess the dermal corrosion potential of chemicals in a weight-of-evidence approach in an integrated testing scheme [e.g., OECD Globally Harmonised Classification System (OECD, 1998); OECD Revised Proposals for Updated Test Guidelines 404 and 405: Dermal and Eye Corrosion/Irritation Studies (OECD, 2001a)]. These integrated testing schemes for dermal irritation/corrosion allow for the use of validated and accepted in vitro methods. In this approach, positive in vitro corrosivity responses do not generally require further testing and can be used for classification and labeling. Negative in vitro corrosivity responses shall be followed by in vivo dermal corrosion/irritation testing. (Note: The first animal used in the irritation/corrosivity assessment would be expected to identify any chemical corrosives that were false negatives in the in vitro test). Furthermore, as is appropriate for any in vitro assay, there is the opportunity for confirmatory testing if false positive results are indicated on a weight of evidence evaluation of supplemental information, such as pH, structure activity relationships (SAR), and other chemical and testing information.

Additional Information About ICCVAM and NICEATM

ICCVAM, with 15 participating Federal agencies, was established in 1997 to coordinate interagency issues on toxicological test method development, validation, regulatory acceptance, and national and international harmonization. The ICCVAM Authorization Act of 2000 (Public Law 106–545) formally authorized and designated ICCVAM as a permanent committee administered by the NIEHS with specific duties that include the technical evaluation of new and alternative testing methods. ICCVAM is charged with developing test recommendations based on those technical evaluations, and forwarding these to Federal agencies for their consideration. The NICEATM was established in 1998 to coordinate and facilitate ICCVAM activities, to provide peer review for validation activities and to promote communication with stakeholders. The NICEATM is located at the NIEHS, Research Triangle Park, NC. Additional information concerning ICCVAM and NICEATM can be found on the ICCVAM/NICEATM web site at *http://iccvam.niehs.nih.gov*.

References

Anon. EU Commission Directive 2000/33/EC of 25 April 2000 (Official Journal of the European Communities), Skin Corrosion, Rat Skin TER and Human Skin Model Assay. OJ L 136, June 8, 2000. Available: *http://embryo.ib.amwaw.edu.pl/invittox/prot/1_13620000608en00010089.pdf* [cited July 19, 2001].

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Balls M, Corcelle G. ''Statement on the scientific validity of the Rat Skin Transcutaneous Electrical Resistance (TER) Test (an in vitro test for skin corrosivity) and Statement of the scientific validity of the EPISKIN™ test (an in vitro test for skin corrosivity),'' dated April 3, 1998. Statement from the European Commission Joint Research Centre, Environment Institute, Ispra (VA), Italy presenting the results of the 10th ECVAM Scientific Advisory Committee (ESAC) meeting on March 31 (1998). Available: *http://www.iivs.org/news/ratskin-episkin.html* [cited July 19, 2001].

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Organization for Economic Co-operation and Development (OECD). Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances, as endorsed by the 28th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, OECD, Paris, France. (November 1998) *http://www.oecd.org/ehs/Class/HCL6.htm*

OECD. OECD Revised Proposals for Updated Test Guidelines 404 and 405: Dermal and Eye Corrosion/Irritation Studies. [OECD ENV/JM/TG (2001)2]. OECD Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. Test Guidelines Programme. Circulated in preparation for the 13th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme, OECD, Paris, France. (2001a)

Dated: September 21, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 01–24371 Filed 9–27–01; 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 Toxicology Program (NTP)

Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity; Guidance Document on Using In Vitro Data to Estimate In Vivo Starting Doses for Acute Toxicity: Notice of Availability and Request for Public Comment.

Summary

Notice is hereby given of the availability of the reports entitled, ''Report of the International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity'' NIH Publication 01–4499 and ''Guidance Document on Using In Vitro Data to Estimate In Vivo Starting Doses for Acute Toxicity'' NIH Publication 01–4500. The Report provides conclusions and recommendations from expert scientists based on their review of current in vitro methods for assessing acute toxicity at an October 17–20, 2000 workshop. The workshop was organized by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The Guidance Document

provides Standard Operating Procedures (SOPs) for performing two in vitro basal cytotoxicity assays and describes how to use this in vitro data to predict starting doses for in vivo acute oral toxicity studies.

Availability of the Documents

To receive a copy of either report, please contact NICEATM at P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709 (mail), 919–541–3398 (phone), 919–541–0947 (fax), or *niceatm@niehs.nih.gov* (email). The reports are also available on the ICCVAM/NICEATM website at *http://iccvam.niehs.nih.gov.*

Request for Public Comments

NICEATM invites written public comments on the Workshop Report and the Guidance Document. Comments should be sent to NICEATM by November 13, 2001. Comments submitted via e-mail are preferred; the acceptable file formats are MS Word (Office 98 or older), plain text, or PDF. Comments should be sent to Dr. William S. Stokes, Director, NICEATM, NIEHS, MD EC–17, PO Box 12233, Research Triangle Park, NC, 27709; telephone 919–541–2384; fax 919–541–0947; e-mail *niceatm@niehs.nih.gov.* Persons submitting written comments should include their contact information (name, affiliation, address, telephone and fax numbers, and e-mail) and sponsoring organization, if any. Public comments received in response to this **Federal Register** notice will be posted on the NICEATM/ICCVAM web site (*http://iccvam.niehs.nih.gov*).

Background

The International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity was held October 17–20, 2000, at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA 22202. The workshop was organized by the NICEATM and ICCVAM, and sponsored by the NIEHS, the NTP, and U.S. EPA. The objectives of the workshop were (1) to assess the current validation status of in vitro test methods that might be useful for assessing the acute systemic toxicity potential of chemicals and (2) to develop recommendations for future research, development, and validation studies that might further enhance the use of in vitro methods for this purpose.

A **Federal Register** notice (Vol. 65, No. 115, pp. 37400–37403, June 14, 2000) requested information and data that should be considered at the workshop, and nominations of expert scientists to participate in the workshop. A second **Federal Register** notice (Vol. 65, No. 184, pp. 57203–57205, September 21, 2000) announced availability of the workshop agenda, registration information, and a background summary of available in vitro methods.

At the workshop, the invited expert scientists were divided into four breakout groups as follows:

Breakout Group 1: In Vitro Screening Methods for Assessing Acute Toxicity
Breakout Group 2: In Vitro Methods for Toxicokinetic Determinations
Breakout Group 3: In Vitro Methods for Predicting Organ-Specific Toxicity
Breakout Group 4: Chemical Data Sets for Validation of In Vitro Acute Toxicity Test Methods

Each breakout group subsequently prepared a written report that represented the consensus of the invited scientists assigned to that group and these reports are included in the Workshop Report. It also includes as appendices: A detailed workshop agenda; summary minutes of plenary sessions and public comments; the background document for workshop participants; a NICEATM summary of the Multicenter Evaluation of In Vitro Cytotoxicity (MEIC); a summary of Federal regulations on acute toxicity; related **Federal Register** notices; and ICCVAM test method recommendations. The ICCVAM test recommendations were developed following the workshop to forward to Federal agencies in accordance with Pub. L. 106–545.

The Breakout Group on In Vitro Screening Methods recommended preparation of a document that would provide guidance on how to use in vitro data to estimate starting doses for in vivo acute toxicity studies. Three scientists subsequently collaborated with the NICEATM to develop a ''Guidance Document on Using In Vitro Data to Estimate In Vivo Starting Doses for Acute Toxicity''. The Guidance Document provides SOPs for conducting two in vitro cytotoxicity tests (the BALB/c 3T3 Neutral Red Uptake (NRU) and the Normal Human Keratinocyte (NHK) NRU assays) and instruction for using these assays to estimate starting doses for in vivo testing. The Guidance Document also includes the ZEBET (German National Centre for the Documentation and Evaluation of Alternatives to Animal Experimentation) Registry of Cytotoxicity (RC) Regression Analysis that provides a mathematical relationship between acute oral systemic rodent toxicity and in vitro basal cytotoxicity using data for 347 chemicals (Halle, 1998; Spielmann et al., 1999). The Guidance Document expands on an approach suggested by Spielmann and colleagues that—as an initial step—the relationship found with the RC data be used to predict starting doses for subsequent in vivo acute lethality assays.

Additional Information About ICCVAM and NICEATM

ICCVAM, with 15 participating Federal agencies, was established in 1997 to coordinate interagency issues on toxicological test method development, validation, regulatory acceptance, and national and international harmonization. The ICCVAM Authorization Act of 2000 (Pub. L. 106–545) formally authorized and designated ICCVAM as a permanent committee administered by the NIEHS with specific duties that include the technical evaluation of new and alternative testing methods. ICCVAM is charged with developing test recommendations based on those technical evaluations, and forwarding these to Federal agencies for their consideration. The NICEATM was established in 1998 to coordinate and facilitate ICCVAM activities, to provide peer review for validation activities and to promote communication with stakeholders. The NICEATM is located at the NIEHS, Research Triangle Park, NC. Additional information concerning ICCVAM and NICEATM can be found on the ICCVAM/NICEATM web site at *http://iccvam.niehs.nih.gov.* In accordance with Public Law 106–545, the Workshop Report and the Guidance Document will be forwarded with ICCVAM test recommendations to Federal agencies for their consideration.

References

Halle, W. 1998. Toxizitätsprüfungen in Zellkulturen für eine Vorhersage der akuten Toxizität (LD_{50}) zur Einsparung von Tierversuchen. Life Sciences/Lebenswissenschaften, Volume 1, 94 pp., Jülich: Forschungszentrum Jülich.

Spielmann, H., E. Genschow, M. Liebsch, and W. Halle. 1999. Determination of the starting dose for acute oral toxicity (LD_{50}) testing in the up and down procedure (UDP) from cytotoxicity data. ATLA 27: 957–966.

Dated: September 18, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 01–24370 Filed 9–27–01; 8:45 am]

BILLING CODE 4140–01–P

signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent applications.

SUPPLEMENTARY INFORMATION: Gaucher Disease is a rare inborn error of metabolism which affects between 10,000 and 20,000 people worldwide, 40% in the United States. Gaucher Disease is the most common lipid storage disease. The symptoms associated with Gaucher Disease result from the accumulation of a lipid called glucocerebroside. This lipid is a byproduct of the normal recycling of red blood cells. When the gene with the instructions for producing an enzyme to break down this byproduct is defective, the lipid accumulates. The lipid is found in many places in the body, but most commonly in the macrophages in the bone marrow. There it interferes with normal bone marrow functions, such as production of platelets (leading to bleeding and bruising) and red blood cells (leading to anemia) and potentially death. The presence of glucocerebroside seems to also trigger the loss of minerals in the bones, causing the bones to weaken, and can interfere with the bone's blood supply.

The field of use is directed to the development of therapies for remedying enzyme deficiencies in the treatment of Gaucher Disease.

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 404.7. The prospective exclusive license may be granted unless, within ninety (90) days from the date of this published notice, NIH receives written evidence and argument that establishes 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 filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections submitted in response 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: September 11, 2000.

Jack Spiegel,

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

[FR Doc. 00–24241 Filed 9–20–00; 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 Institutes of Health (NIH), National Toxicology Program (NTP); Notice of an International Workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity, co-sponsored by NIEHS, NTP and the U.S. Environmental Protection Agency (EPA): Workshop Agenda and Registration Information

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by NIEHS, the NTP, and the EPA, and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The agenda topic is a scientific workshop to assess the current status of *in vitro* test methods for evaluating the acute systemic toxicity potential of chemicals and to develop recommendations for future research, development, and validation studies. The workshop will take place on October 17–20, 2000, at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA, 22202. The meeting will be open to the public.

In a previous **Federal Register** notice (Vol. 65, No. 115, pp. 37400–37403), ICCVAM requested information and data that should be considered at the Workshop and nominations of expert scientists to participate in the Workshop. A preliminary list of relevant studies to be considered for the Workshop was also provided. As a result of this request, an ICCVAM interagency Workshop Organizing Committee has selected an international group of scientific experts to participate in this Workshop. NICEATM, in collaboration with ICCVAM, has developed a background summary of data and performance characteristics for available *in vitro* methods. This summary will be made available to invited expert scientists and the public before the Workshop. Requests for the summary can be made to the address given below. This notice provides an agenda, registration information, and updated details about the Workshop.

Workshop Background and Scope

A. Background

Acute toxicity testing is conducted to determine the hazards of various chemicals and products. This information is used to properly classify and label materials as to their lethality in accordance with an internationally harmonized system (OECD, 1998). Non-lethal endpoints may also be evaluated to identify potential target organ toxicity, toxicokinetic parameters, and dose-response relationships. While animals are currently used to evaluate acute toxicity, recent studies suggest that *in vitro* methods may also be helpful in predicting acute toxicity.

Studies by Spielmann *et al.* (1999) suggest that *in vitro* cytotoxicity methods may be useful in predicting a starting dose for *in vivo* studies, and thus may potentially reduce the number of animals necessary for such determinations. Other studies (*e.g.,* Ekwall *et al.,* 2000) have indicated an association between chemical concentrations leading to *in vitro* cytotoxicity and human lethal blood concentrations. A program to assess toxicokinetics and target organ toxicity utilizing *in vitro* methods has been proposed that may provide enhanced predictions of toxicity and potentially reduce or replace animal use for some tests (Ekwall *et al.,* 1999). However, many of the necessary *in vitro* methods for this program have not yet been developed. Other methods have not been evaluated in validation studies to determine their usefulness and limitations for generating information to meet regulatory requirements for acute toxicity testing. Development and validation of *in vitro* methods which can establish accurate dose-response relationships will be necessary before such methods can be considered for the reduction or replacement of animal use for acute toxicity determinations.

This workshop will examine the status of available *in vitro* methods for assessing acute toxicity. This includes screening methods for acute toxicity, such as methods that may be used to predict the starting dose for *in vivo* animal studies, and methods for generating information on toxicokinetics, target organ toxicity, and mechanisms of toxicity. The workshop will develop recommendations for validation efforts necessary to characterize the usefulness and limitations of these methods. Recommendations will also be developed for future mechanism-based research and development efforts that might further improve *in vitro* assessments of acute systemic lethal and non-lethal toxicity.

B. Objectives of the Workshop

Four major topics will be addressed:

- *In Vitro* Screening Methods for Assessing Acute Toxicity;

• *In Vitro* Methods for Toxicokinetic Determinations;
• *In Vitro* Methods for Predicting Organ Specific Toxicity; and
• Chemical Data Sets for Validation of *In Vitro* Acute Toxicity Test Methods.

The objectives of the meeting are to:

1. Review the status of *in vitro* methods for assessing acute systemic toxicity:

a. Review the validation status of available *in vitro* screening methods for their usefulness in estimating *in vivo* acute toxicity,

b. Review *in vitro* methods for predicting toxicokinetic parameters important to acute toxicity (*i.e.,* absorption, distribution, metabolism, elimination), and

c. Review *in vitro* methods for predicting specific target organ toxicity;

2. Recommend candidate methods for further evaluation in prevalidation and validation studies;

3. Recommend validation study designs that can be used to characterize adequately the usefulness and limitations of proposed *in vitro* methods;

4. Identify reference chemicals that can be used for development and validation of *in vitro* methods for assessing *in vivo* acute toxicity; and

5. Identify priority research efforts necessary to support the development of mechanism-based *in vitro* methods to assess acute systemic toxicity. Such efforts might include incorporation and evaluation of new technologies, such as gene microarrays, and development of methods necessary to generate dose response information.

Workshop Information

A. Workshop Agenda

Tuesday, October 17, 2000

8:30 a.m.—Opening Plenary Session
• Workshop Introduction
• Welcome from the National Toxicology Program (NTP)
• Overview of ICCVAM and NICEATM
• Acute Toxicity: Historical and Current Regulatory Perspectives
• Acute Toxicity Data: A Clinical Perspective

10:30 a.m.—*In Vitro* Approaches to Estimate the Acute Toxicity Potential of Chemicals
• Estimating Starting Doses for *In Vivo* Studies using *In Vitro* Data
• An Integrated Approach for Predicting Systemic Toxicity
• Opportunities for Future Progress
Public Comment
Breakout Groups' Charges
12:30 p.m.—Lunch Break

1:45 p.m.—Breakout Groups: Identifying What Is Needed from *In Vitro* Methods
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
5:30 p.m.—Adjourn for the Day

Wednesday, October 18, 2000

8:00 a.m.—Plenary Session—Status Reports by Breakout Group Co-Chairs
9:00 a.m.—Breakout Groups: Current Status of *In Vitro* Methods for Acute Toxicity
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
12:00 p.m.—Lunch Break
1:30 p.m.—Breakout Groups: Current Status of *In Vitro* Methods for Acute Toxicity (Cont'd)
5:30 p.m.—Adjourn for the Day

Thursday, October 19, 2000

8:00 a.m.—Plenary Session—Status Reports by Breakout Group Co-Chairs
9:00 a.m.—Breakout Groups: Future Directions for *In Vitro* Methods for Acute Toxicity
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
12:00 p.m.—Lunch Break
1:30 p.m.—Breakout Groups: Future Directions for *In Vitro* Methods for Acute Toxicity (Cont'd)
5:30 p.m.—Adjourn for the Day

Friday, October 20, 2000

8:00 a.m.—Closing Plenary Session—Reports by Breakout Group Co-Chairs
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
Public Comment
Closing Comments
12:15 p.m.—Adjourn

B. Workshop Registration

The Workshop meeting will be open to the public, limited only by the space available. Due to space limitations, advance registration is requested by October 13, 2000. Registration forms can be obtained by contacting NICEATM at the address given below or by accessing the on-line registration form at: *http://iccvam.niehs.nih.gov/invi_reg.htm.* Other relevant Workshop information (*i.e.,* accommodations, transportation, etc.) is also provided at this website.

C. Public Comment

The Public is invited to attend the Workshop and the number of observers will be limited only by the space available. Two formal public comment sessions on Tuesday, October 17th and Friday, October 20th will provide an opportunity for interested persons or groups to present their views and comments to the Workshop participants (please limit to one speaker per group). Additionally, time will be allotted during each of the Breakout Group sessions for general discussion and comments from observers and other participants. The Public is invited to present oral comments or to submit comments in writing for distribution to the Breakout Groups to NICEATM at the address given below by October 13, 2000. Oral presentations will be limited to seven minutes per speaker to allow for a maximum number of presentations. Individuals presenting oral comments are asked to provide a hard copy of their statement at registration. For planning purposes, persons wishing to give oral comments are asked to check the box provided on the Registration Form, although requests for oral presentations will also be accepted on-site (subject to availability of time). Persons registering for oral comments or submitting written remarks are asked to include their contact information (name, address, affiliation, telephone, fax, and e-mail).

Guidelines for Requesting Registration Form and Submission of Public Comment

Requests for registration information and submission of public comments should be directed to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, MD EC–17, PO Box 12233, Research Triangle Park, NC 27709; 919–541–3398 (phone); 919–541–0947 (fax); *iccvam@niehs.nih.gov* (e-mail). Public comments should be accompanied by complete contact information including name, (affiliation, if applicable), address, telephone number, and e-mail address.

References

• OECD (Organisation for Economic Cooperation and Development). (1998). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances. OECD, Paris. (website: *http://www.oecd.org//ehs/Class/HCL6.HTM*)
• Spielmann, H., Genschow, E., Leibsch, M., and Halle, W. (1999) Determination of the starting dose for

acute oral toxicity (LD50) testing in the up and down procedure (UDP) from cytotoxicity data. ATLA, 27(6), 957–966.

• Ekwall, B., Ekwall, B., and Sjorstrom, M. (2000) MEIC evaluation of acute systemic toxicity: Part VIII. Multivariate partial least squares evaluation, including the selection of a battery of cell line tests with a good prediction of human acute lethal peak blood concentrations for 50 chemicals. ATLA, 28, Suppl. 1, 201–234.

• Ekwall, B., Clemedson, C., Ekwall, B., Ring, P., and Romert, L. (1999) EDIT: A new international multicentre programme to develop and evaluate batteries of *in vitro* tests for acute and chronic systemic toxicity. ATLA 27, 339–349.

Dated: September 12, 2000.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 00–24244 Filed 9–20–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4463–N–04]

Notice of FHA Debenture Call

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This Notice announces a debenture recall of certain Federal Housing Administration debentures, in accordance with authority provided in the National Housing Act.

FOR FURTHER INFORMATION CONTACT: Richard Keyser, Room 3119P, L'Enfant Plaza, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755–7510 x137. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Pursuant to Sections 204(c) and 207(j) of the National Housing Act, 12 U.S.C. 1710(c), 1713(j), and in accordance with HUD's regulation at 24 CFR 203.409 and § 207.259(e)(3), the Federal Housing Commissioner, with approval of the Secretary of the Treasury, announces the call of all Federal Housing Administration debentures, with a coupon rate of 6.625 percent or above, except for those debentures subject to ''debenture lock agreements'', that have been registered on the books of the Federal Reserve Bank of Philadelphia, and are, therefore, ''outstanding'' as of September 30, 2000. The date of the call is January 1, 2001.

The debentures will be redeemed at par plus accrued interest. Interest will cease to accrue on the debentures as of the call date. Final interest on any called debentures will be paid with the principal at redemption.

During the period from the date of this notice to the call date, debentures that are subject to the call may not be used by the mortgagee for a special redemption purchase in payment of a mortgage insurance premium.

No transfer of debentures covered by the foregoing call will be made on the books maintained by the Treasury Department on or after October 1, 2000. This does not affect the right of the holder of a debenture to sell or assign the debenture on or after this date. Payment of final principal and interest due on January 1, 2001, will be made automatically to the registered holder.

Dated: September 15, 2000.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 00–24288 Filed 9–20–00; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–841026

Applicant: Thane Wibbels, University of Alabama at Birmingham, Birmingham, AL

The applicant requests a permit to import up to 1000 blood samples and up to 500 tissue samples taken from Kemp's Ridley sea turtles (*Lepidochelys kempii*) in Mexico for enhancement of the species through scientific research. This notification covers activities conducted by the applicant over a five year period.

PRT–032758

Applicant: Exotic Feline Breeding Compound, Inc., Rosamond, CA

The applicant requests a permit to import 1 captive-born male Amur leopard (*Panthera pardus orientalis*) from the Novosibirsk Zoo, Russia for the purpose of propagation for the enhancement of the survival of the species.

PRT–032757

Applicant: Omaha's Henry Doorly Zoo, Omaha, NE

The applicant requests a permit to import 1 captive-born female Sumatran tiger (*Panthera tigris sumatrae*) from the Surabaya Zoo, Indonesia for the purpose of propagation for the enhancement of the survival of the species.

PRT–031061

Applicant: Susan E. Aronoff, Tampa, FL, 33624

The applicant requests a permit to import 1 captive-born male cheetah (*Acinonyx jubatus*) from the Endangered Animal Foundation, Driftweg, the Netherlands to enhance the survival of the species through conservation education.

PRT–830414

Applicant: Duke University Primate Center, Durham, NC

The applicant requests re-issuance of a permit to import two male and three female wild-caught golden-crowned sifakas (*Propithecus tattersalli*) from Dariana, Madagascar for the purpose of propagation for the enhancement of the survival of the species. This notification covers requests for re-issuances of the permit by the applicant over a five year period.

PRT–808256

Applicant: Duke University Primate Center, Durham, NC

The applicant requests re-issuance of a permit to import one male and two female wild-caught diademed sifakas (*Propithecus diadema*) from the Department of Water and Forest, Maramize, Madagascar for the purpose of propagation for the enhancement of the survival of the species. This notification covers requests for re-issuances of the permit by the applicant over a five year period.

PRT–031796

Applicant: Larry Edward Johnson, Boerne, TX

The applicant requests a permit to export two male and two female captive-born ring-tailed lemurs (*Catta lemur*) to Munchi's Zoo, Buenos Aires, Argentina to enhance the survival of the species through conservation education and captive propagation.

PRT–026102

Applicant: Elizabeth G. Stone/University of Georgia, Athens, GA

The applicant requests a permit to import salvaged specimens, non-viable eggs, and biological samples from Thick-billed parrots (*Rhynchopsitta pachyrhyncha*) collected in the wild in Mexico, for scientific research. This

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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB 4 (01).

Date: June 16, 2000.

Time: 8:00 am to 2:00 pm.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 1300 Concourse Drive, Linthicum, Maryland 21090.

Contact Person: William E. Elzinga, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 647, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8895.

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. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 8, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–14960 Filed 6–13–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Institute of Nursing Research; 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: National Institute of Nursing Research Special Emphasis Panel, NINR Career Transitional Award Applications (K22s).

Date: June 21, 2000.

Time: 3:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20852.

Contact Person: Mary J. Stephens-Frazier, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, Natcher Building, Room 3AN32, (301) 594–5971.

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. 93.361, Nursing Research, National Institute of Health, HHS)

Dated: June 8, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy

[FR Doc. 00–14963 Filed 6–13–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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: National Institute of Nursing Research Special Emphasis Panel, NINR/ORMH Mentored Research Scientist Development Award for Minority Investigators (KO1s).

Date: June 21, 2000.

Time: 8:30 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mary J. Stephens-Frazier, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, Natcher Building, Room 3AN32, Bethesda, MD 20892, (301) 594–5971.

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. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: June 8, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–14964 Filed 6–13–00; 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 Institutes of Health (NIH), National Toxicology Program (NTP); Notice of an International Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity, co-sponsored by NIEHS, NTP and the U.S. Environmental Protection Agency (EPA): Request for Data and Suggested Expert Scientists

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by NIEHS, the NTP, and the EPA, and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The agenda topic is a scientific workshop to assess the current status of in vitro test methods for evaluating the acute systemic toxicity potential of chemicals, and to develop recommendations for future development and validation studies. The workshop will take place on October 17–20, 2000 at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA, 22202. The meeting will be open to the public.

In preparing for this Workshop, ICCVAM is requesting: (1) Information and data that should be considered at the Workshop, including relevant data on currently available in vitro methods for assessing acute systemic toxicity; and (2) nominations of expert scientists to participate in the Workshop. An agenda, registration information, and other details will be provided in a subsequent **Federal Register** notice.

Background

ICCVAM, with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to coordinate issues relating to the development, validation, acceptance, and national/international harmonization of toxicological test methods. ICCVAM seeks to promote the scientific validation and regulatory acceptance of new and improved test methods applicable to Federal agencies, including methods that may reduce or replace animal use, or that refine protocols to lessen animal pain and distress. The Committee's functions include the coordination of interagency reviews of toxicological test methods and communication with stakeholders throughout the process of test method development and validation. The following Federal regulatory and research agencies participate:

Consumer Product Safety Commission
Department of Defense
Department of Energy
Department of Health and Human Services
  Agency for Toxic Substances and Disease Registry
  Food and Drug Administration
  National Institute for Occupational Safety and Health/CDC
  National Institutes of Health
  National Cancer Institute
  National Institute of Environmental Health Sciences
  National Library of Medicine
Department of the Interior
Department of Labor
  Occupational Safety and Health Administration
Department of Transportation
  Research and Special Programs Administration
Environmental Protection Agency

NICEATM was established in 1998 and provides operational support for the ICCVAM. NICEATM and ICCVAM collaborate to carry out activities associated with the development, validation, and regulatory acceptance of proposed new and improved test methods. These activities may include:

- Test Method Workshops, which are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new testing methods, to identify research efforts that may be needed to develop new test methods, and to identify appropriate development and validation activities for proposed new methods.
- Expert Panel Meetings, which are typically convened to evaluate the validation status of a method following the completion of initial development and pre-validation studies. Expert Panels are asked to recommend additional validation studies that might be helpful in further characterizing the usefulness of a method, and to identify any additional research and development efforts that might enhance the effectiveness of a method.
- Independent Peer Review Panel Meetings, which are typically convened following the completion of comprehensive validations studies on a test method. Peer Review Panels are asked to develop scientific consensus on the usefulness and limitations of test methods to generate information for specific human health and/or ecological risk assessment purposes. Following the independent peer review of a test method, ICCVAM forwards recommendations on its usefulness to agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

Additional information about ICCVAM and NICEATM can be found at the website: *http://iccvam.niehs.nih.gov.*

Workshop Background and Scope

A. Background

Federal regulatory agencies require toxicity testing to determine the safety or hazard of various chemicals and products prior to human exposure. Agencies use this information to properly classify and label products as to their hazard potential. Acute oral toxicity determinations are currently made using animals. However, recent studies (e.g., Spielmann et al., 1999) suggest that in vitro cytotoxicity methods may be useful in predicting a starting dose for in vivo studies, and thus may potentially reduce the number of animals necessary for such determinations.

Other studies (e.g., Ekwall et al., 2000) have indicated an association between in vitro cytotoxicity and human lethal blood concentrations. However, these in vitro methods have not yet been evaluated in validation studies to determine their usefulness and limitations for generating acute toxicity testing information necessary to meet regulatory testing requirements. Additionally, other in vitro methods would likely be necessary to establish accurate dose-response relationships before such methods could substantially reduce or replace animal use for acute toxicity determinations.

This workshop will examine the status of available in vitro methods and develop recommendations for validation efforts necessary to characterize the usefulness and limitations of existing methods. Recommendations for future research and development efforts that might further enhance the usefulness of in vitro assessments of acute systemic lethal toxicity will also be developed.

B. Objectives of the Workshop

Four major topics will be addressed:

1. General cytotoxicity methods predictive of acute lethal toxicity;
2. Toxicokinetic and organ specific toxicity methods;
3. Reference chemicals for validation of the above methods; and
4. The use of quantitative structure activity relationships (QSAR) and chemical/physical properties for predicting acute lethal toxicity.

The objectives of the meeting are to:

1 a. Identify and review the status of in vitro general cytotoxicity screening methods that may reduce animal use for assessing acute systemic toxicity;

b. Identify information from in vitro methods necessary to predict acute systemic toxicity and review the status of relevant methods (*e.g.,* in vitro methods to assess gut absorption, metabolism, blood-brain barrier penetration, volume distribution to critical target organs, and specific target organ toxicity);

2. Identify candidate methods for further evaluation in prevalidation and validation studies;

3. Identify reference chemicals useful for development and validation of in vitro methods for assessing acute systemic toxicity;

4. Identify validation study designs needed to adequately characterize the proposed methods in 2.; and

5. Identify priority research efforts necessary to support the development of in vitro methods to adequately assess acute systemic toxicity. Such efforts might include incorporation and evaluation of new technologies such as gene microarrays, and development of methods necessary to generate dose response information.

C. Methods for Consideration

Given the breadth of the workshop topics, many methods are likely to be considered relevant to the discussion. Methods will include but are not limited to those proposed in the Multicentre Evaluation of In Vitro Cytotoxicity (MEIC) battery (*http://www.ctlu.se*). A background document summarizing the data and performance characteristics for available methods is being prepared by NICEATM in collaboration with the ICCVAM interagency organizing committee. Information received as a result of this **Federal Register** notice will be

considered for inclusion in the background document. In formulating its recommendations, the Workshop participants will evaluate information in the background document and relevant information from other sources.

D. Test Method Data and Information Sought

Data are sought from completed, ongoing, or planned studies that provide comparative performance data for in vitro methods compared to currently accepted in vivo methods for determining acute lethal toxicity and hazard classification. Data from test methods that provide toxicokinetic and specific target organ toxicity information are also sought. Submissions should describe the extent to which established criteria for validation and regulatory acceptance have been addressed. These criteria are provided in ''Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods,'' NIH publication 97–3981 (*http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/iccvam.html*). Where possible, submitted data and information should adhere to the guidance provided in the document, ''Evaluation of the Validation Status of Toxicological Methods: General Guidelines for Submissions to ICCVAM,'' NIH Publication 99–4496, (*http://iccvam.niehs.nih.gov/doc1.htm*). Both publications are also available on request from NICEATM at the address provided below. Relevant information submitted in response to this request will be incorporated into the background material provided to Workshop participants. A preliminary list of relevant studies is provided at the end of this announcement, and public comment and suggestions for additions are invited.

NICEATM and the ICCVAM interagency workshop organizing committee will compile information on the studies to be considered at the Workshop. All data should be submitted by July 15, 2000 in order to ensure full consideration.

E. Request for Nomination of Expert Scientists for the Test Method Workshop

NICEATM is soliciting nominations for expert scientists to participate in the Workshop. (See Guidelines for Submission of Comments below). Types of expertise likely to be relevant include acute toxicity testing in animals, evaluation and treatment of acute toxicity in humans, development and use of in vitro methodologies, statistical data analysis, knowledge of chemical data sets useful for validation of acute toxicity studies, and hazard classification of chemicals and products. Expertise need not be limited to these areas, nor will these areas necessarily be included on the Panel. An appropriate breadth of expertise will be sought. If other areas of scientific expertise are recommended, the rationale should be provided.

Nominations should be accompanied by complete contact information including name, address, institutional affiliation, telephone number, and e-mail address. The rationale for nomination should be provided. If possible, a biosketch or a curriculum vitae should be included. To avoid the potential for candidates being contacted by a large number of nominators, candidates need not be contacted prior to nomination.

Workshop experts will be selected by an ICCVAM interagency workshop organizing committee after considering all nominations received from the public as well as nominations developed internally. All nominees will be contacted for interest and availability, and curricula vitae will be solicited from the nominees. Candidates will be required to disclose potential conflicts of interest.

Schedule for the Workshop

The Workshop will take place on October 17–20, 2000 at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA 22202. The Workshop meeting will be open to the public, limited only by space available.

Submitted methods and supporting data will be reviewed during the July to August 2000 timeframe and a background review document will be prepared by NICEATM in collaboration with the ICCVAM interagency organizing committee. The background information will be made available to Workshop experts for discussion at the meeting and will be available to the Public in advance of the Workshop.

Public Input Invited

As described above, ICCVAM invites comments on the scope and process for the review; comments on the ICCVAM preliminary list of studies for consideration; the submission of other test methods for consideration; and the nomination of experts to participate in the Workshop. Nominations must be submitted within 30 days of the publication date of this notice, and other information should be submitted by July 15, 2000.

Guidelines for Submission of Public Comment

Correspondence should be directed to Dr. William S. Stokes, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, MD EC–17, PO Box 12233, Research Triangle Park, NC 27709; 919–541–3398 (phone); 919–541–0947 (fax); *iccvam@niehs.nih.gov* (e-mail). Public comments should be accompanied by complete contact information including name, (affiliation, if applicable), address, telephone number, and e-mail address.

Preliminary List of Studies to be Considered for the Workshop on In Vitro Methods for Assessing Acute Systemic Toxicity

ICCVAM has compiled a preliminary list of relevant studies. The public is invited to comment on this list, and suggestions for additions may be submitted. (See Section of this **Federal Register** announcement on Guidelines for Submission of Public Comments).

Studies that may be completed but not published are not included here. This list provides examples of studies and information that may be appropriate for consideration by the Workshop experts.

Balls, M., Blaauboer, B.J., Fentem, J.H., Bruner, L., Combes, R.D., Ekwall, B., Fielder, R.J., Guillouzo, A., Lewis, R.W., Lovell, D.P., Reinhardt, C.A., Repetto, G., Sladowski, D., Spielmann, H., and Zucco, F. (1995) Practical aspects of the validation of toxicity test procedures—The report and recommendations of ECVAM Workshop 5. ATLA 23, 129–147.

Bernson, V., Bondesson, I., Ekwall, B., Stenberg, K., and Walum, E. (1987) A multicenter evaluation study of *in vitro* cytotoxicity. ATLA, 14, 144–145.

Bondesson, I., Ekwall, B., Stenberg, K., Romert, L., and Walum, E. (1988) Instruction for participants in the multicenter evaluation study of *in vitro* cytotoxicity (MEIC). ATLA, 15, 191–193.

Bondesson, I., Ekwall, B., Hellberg, S., Romert, L., Stenberg, K., and Walum, E. (1989) MEIC—A new international multicenter project to evaluate the relevance to human toxicity of *in vitro* cytotoxicity tests. Cell Biol. Toxicol., 5, 331–347.

Clemedson, C., and Ekwall, B. (1999) Overview of the final MEIC results: I. The *in vitro-in vivo* evaluation. Toxicology In vitro, 13, 657–663.

Clemedson, C., McFarlane-Abdulla, E., Andersson, M., Barile, F.A., Calleja, M.C., Chesnea, C., Clothier, R., Cottin, M., Curren, R., Daniel-Szolgay, E., Dierickx, P., Ferro, M., Fiskesj'', G., Garza-Ocanas, L., Goamez-Lechoan, M.J., Gualden, M., Isomaa, B., Janus, J., Judge, P., Kahru, A., Kemp, R.B., Kerszman, G., Kristen, U., Kunimoto, M., Karenlampi, S., Lavrijsen, K., Lewan L., Lilius, H., Ohno, T., Persoone, G., Roguet, R.,

Romert, L., Sawyer, T., Seibert, H., Shrivastava, R., Stammati, A., Tanaka, N., Torres Alanis, O., Voss, J–U., Wakuri, S., Walum, E., Wang, X., Zucco, F., and Ekwall, B. (1996) MEIC evaluation of acute systemic toxicity. Part I. Methodology of 68 *in vitro* toxicity assays used to test the first 30 reference chemicals. ATLA, 24, Suppl. 1, 249–272.

Clemedson, C., McFarlane-Abdulla, E., Andersson, M., Barile, F.A., Calleja, M.C., Chesne, C., Clothier, R., Cottin, M., Curren, R., Dierickx, P., Ferro, M., Fiskesja, G., Garza-Ocanas, L., Gomez-Lechon, M.J., Gulden, M., Isomaa, B., Janus, J., Judge, P., Kahru, A., Kemp, R.B., Kerszman, G., Kristen, U., Kunimoto, M., Karenlampi, S., Lavrijsen, K., Lewan L., Lilius, H., Malmsten, A., Ohno, T., Persoone, G., Pettersson, R., Roguet, R., Romert, L., Sandberg, M., Sawyer, T., Seibert, H., Shrivastava, R., Sjostrom, M., Stammati, A., Tanaka, N., Torres Alanis, O., Voss, J–U., Wakuri, S., Walum, E., Wang, X., Zucco, F. and, Ekwall, B. (1996) MEIC evaluation of acute systemic toxicity. Part II. *In vitro* results from 68 toxicity assays used to test the first 30 reference chemicals and a comparative cytotoxicity analysis. ATLA, 24, Suppl. 1, 273–311.

Clemedson, C., Barile, F.A., Ekwall, B., Gomez-Lechon, M.J., Hall, T., Imai, K., Kahru, A., Logemann, P., Monaco, F., Ohno, T., Segner, H., Sjostrom, M., Valentino, M., Walum, E., Wang, X., and Ekwall, B. (1998). MEIC evaluation of acute systemic toxicity: Part III. *In vitro* results from 16 additional methods used to test the first 30 reference chemicals and a comparative cytotoxicity analysis. ATLA 26, Suppl. 1, 91–129.

Clemedson, C., Aoki, Y., Andersson, M., Barile, F.A., Bassi, A.M., Calleja, M.C., Castano, A., Clothier, R.H., Dierickx, P., Ekwall, B., Ferro, M., Fiskeso, G., Garza-Ocanas, L. Gomez-Lechoan, M.J., Gulden, M., Hall, T., Imai, K., Isomaa, B., Kahru, A., Kerszman, G., Kjellstrand, P., Kristen, U., Kunimoto, M., Karenlampi, S., Lewan, L., Lilius, H., Loukianov, A., Monaco, F., Ohno, T., Persoone, G., Romert, L., Sawyer, T.W., Shrivastava, R., Segner, H., Seibert, H., Sjostrom, M., Stammati, A., Tanaka, N., Thuvander, A., Torres-Alanis, O., Valentino, M., Wakuri, S., Walum, E., Wieslander, A., Wang, X., Zucco, F., and Ekwall, B. (1998). MEIC evaluation of acute systemic toxicity. Part IV. *In vitro* results from 67 toxicity assays used to test reference chemicals 31–50 and a comparative cytotoxicity analysis. ATLA 26, Suppl. 1, 131–183.

Clemedson, C., Barile, F.A., Chesne, C., Cottin, M., Curren, R., Ekwall, B., Ferro, M., Gomez-Lechon, M.J., Imai, K., Janus, J., Kemp, R.B., Kerszman, G., Kjellstrand, P., Lavrijsen, K., Logemann, P., McFarlane-Abdulla, E., Roguet, R., Segner, H., Seibert, H., Thuvander, A., Walum, E., and Ekwall, Bj. (2000) MEIC evaluation of acute systemic toxicity: Part VII. Prediction of human toxicity by results from testing of the first 30 reference chemicals with 27 further *in vitro* assays. ATLA 28, Suppl. 1, 161–200.

Ekwall, B. (1995) The basal cytotoxicity concept, pp 721–725. In Proceedings of the World Congress on Alternatives and Animal Use in the Life Sciences: Education, Research, Testing. Alternative Methods in Toxicology and the Life Sciences, Vol. 11. Mary Ann Liebert, New York, 1995.

Ekwall, B. (1999) Overview of the Final MEIC Results: II. The *In vitro/in vivo* evaluation, including the selection of a practical battery of cell tests for prediction of acute lethal blood concentrations in humans. Toxicol. *In vitro*, 13, 665–673.

Ekwall, B., Gomez-Lechon, M.J., Hellberg, S., Bondsson, I., Castell, J.V., Jover, R., Hogberg, J., Ponsoda, X., Stenberg, K., and Walum, E. (1990) Preliminary results from the Scandinavian multicentre evaluation of *in vitro* cytotoxicity (MEIC). Toxicol. *In vitro,* 4, 688–691.

Ekwall, B., Clemedson, C., Crafoord, B., Ekwall, Ba., Hallander, S., Walum E., and Bondesson, I. (1998) MEIC evaluation of acute systemic toxicity. Part V. Rodent and human toxicity data for the 50 reference chemicals. ATLA 26, Suppl. 2, 569–615.

Ekwall, B., Barile., F.A., Castano, A., Clemedson, C., Clothier, R.H., Dierickx, P., Ekwall, B., Ferro, M., Fiskesjo;, G., Garza-Ocanas, L., Gomez-Lechon, M-J., Gulden, M., Hall, T., Isomaa, B., Kahru, A, Kerszman, G., Kristen, U., Kunimoto, M., Karenlampi, S., Lewan, L, Loukianov, A., Ohno, T., Persoone, G., Romert, L., Sawyer, T.W., Segner, H., Shrivastava, R., Stammati, A., Tanaka, N., Valentino, M., Walum, E., and Zucco, F. (1998) MEIC evaluation of acute systemic toxicity. Part VI. Prediction of human toxicity by rodent LD50 values and results from 61 *in vitro* tests. ATLA 26, Suppl. 2, 617–658.

Ekwall, B., Clemedson, C., Ekwall, B., Ring, P., and Romert, L. (1999) EDIT: A new international multicentre programme to develop and evaluate batteries of *in vitro* tests for acute and chronic systemic toxicity. ATLA 27, 339–349.

Ekwall, B., Ekwall, B., and Sjostrom, M. (2000) MEIC evaluation of acute systemic toxicity: Part VIII. Multivariate partial least squares evaluation, including the selection of a battery cell line tests with a good prediction of human acute lethal peak blood concentrations for 50 chemicals. ATLA 28, Suppl. 1, 201–234.

Hellberg, S., Bondesson, I., Ekwall, B., Gomez-Lechon, M.J., Jover, R., Hogberg, J., Ponsoda, X., Romert, L., Stenberg, K., and Walum, E. (1990) Multivariate validation of cell toxicity data: The first ten MEIC chemicals. ATLA, 17, 237–238.

Hellberg, S., Eriksson, L., Jonsson, J., Lindgren, F., Sjostrom, M., Wold, S., Ekwall, B., Gomez-Lechon, J.M., Clothier, R., Accomando, N.J., Gimes, G., Barile, F.A., Nordin, M., Tyson, C.A., Dierickx, P., Shrivastava, R.S., Tingsleff-Skaanild, M., Garza-Ocanas, L., and Fiskesjo;, G. (1990) Analogy models for prediction of human toxicity. ATLA, 18, 103–116.

Shrivastava, R., Delomenie, C., Chevalier, A., John, G., Ekwall, B., Walum, E., and Massingham, R. (1992) Comparison of *in vivo* acute lethal potency and *in vitro* cytotoxicity of 48 chemicals. Cell Biol. Toxicol., 8(2), 157–170.

Spielmann, H., Genschow, E., Liebsch, M., and Halle, W. (1999) Determination of the starting dose for acute oral toxicity (LD50) testing in the up and down procedure (UDP) from cytotoxicity data. ATLA, 27(6), 957–966.

Walum, E, Nilsson, M, Clemedson, C. and Ekwall, B. (1995) The MEIC program and its implications for the prediction of acute human systemic toxicity, pp 275–282 In Proceedings of the World Congress on Alternatives and Animal Use in the Life Sciences: Education, Research, Testing. Alternative Methods in Toxicology and the Life Sciences, Vol. 11. Mary Ann Liebert, New York, 1995.

Dated: June 6, 2000.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4564–N–03]

Notice of Proposed Information Collection: Lead Hazard Control Grant Program Data Collection—Progress Reporting

AGENCY: Office of Lead Hazard Control.

ACTION: Notice.

SUMMARY: The revised information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: August 14, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Gail Ward, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW, Room P–3206, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Matthew Ammon at (202) 755–1785, ext. 158 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department is submitting the revised information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the revised collection of information is necessary for the proper performance of the functions of the agency, including whether the

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