

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 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 Walcott,**

*Associate Commissioner for External Relations.*

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## 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](mailto: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.*

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