and Radiological Health (HFZ–300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0243.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law. Among other things, MDUMFA authorized the collection of user fees to improve the performance and predictability of FDA's device review program, including premarket approval applications (PMAs). One such goal included a commitment to improve the scheduling and timeliness of PMA preapproval inspections. A portion of the user fees collected under MDUFMA will be used to help to cover the costs associated with the bioresearch monitoring (BIMO) program review of a PMA and the performance of any related clinical or nonclinical inspections. This final guidance document supersedes the corresponding draft guidance entitled ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program,'' which was announced in the **Federal Register** on June 20, 2006 (71 FR 35436 through 35437).

The comment period for the draft guidance closed on September 18, 2006. During this time, FDA received one set of comments from a device manufacturer concerning the draft guidance. Some of the comments suggested combining the BIMO and manufacturing preapproval inspections. FDA did not make changes in response to these comments because preapproval BIMO and manufacturing inspections can not be performed at the same time. Compared to the preapproval manufacturing inspection program, the BIMO program has different objectives, usually involves inspections of different sites, and FDA investigators with different expertise. FDA did modify the guidance to respond to comments that requested further information about criteria for selecting inspection sites and determining when followup actions are necessary.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1602 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control Number 0910–0231.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8–143 Filed 1–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Announcement of an Independent Scientific Peer Review Panel Meeting on the Murine Local Lymph Node Assay; Availability of Draft Background Review Documents; Request for Comments

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

**ACTION:** Meeting announcement and request for comments.

**SUMMARY:** NICEATM in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces an independent scientific peer review panel meeting to evaluate modifications and new applications for the Murine Local Lymph Node Assay (LLNA). The LLNA is an alternative test method that can be used to determine the allergic contact dermatitis potential of chemicals and products. The panel will review the following:

- The validation status of three modified LLNA test method protocols that use non-radioactive probe chemicals.
- The validation status of a LLNA limit dose procedure.
- The use of the LLNA to test mixtures, aqueous solutions, and metals (applicability domain for the LLNA).
- The use of the LLNA to determine potency (potential for causing allergic contact dermatitis).
- Revised draft recommended performance standards for the LLNA.

At this meeting, the panel will peer review the draft background review documents and revised draft LLNA performance standards for each topic and evaluate the extent that established validation and acceptance criteria have been appropriately addressed. The panel will also comment on the extent

that the review documents support draft ICCVAM recommendations on proposed test method protocols, proposed uses of the LLNA, and the revised draft LLNA performance standards.

NICEATM invites public comments on the draft background review documents, draft ICCVAM test recommendations, draft test method protocols, and revised draft LLNA performance standards. All documents will be available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm* by January 8, 2008.

**DATES:** The meeting is scheduled for March 4–6, 2008, from 8:30 a.m. to 5 p.m. each day. The meeting is open to the public free of charge, with attendance limited only by the space available. In order to facilitate planning for this meeting, persons wishing to attend are asked to register by February 20, 2008, via the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/contact/reg_LLNAPanel.htm*). The deadline for written comments is February 22, 2008.

**ADDRESSES:** The meeting will be held at the U.S. Consumer Product Safety Commission (CPSC) Headquarters, Bethesda Towers Bldg., 4330 East West Highway, Bethesda, MD.

**FOR FURTHER INFORMATION CONTACT:** Comments may also be submitted via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm*. Comments or other correspondence can be sent to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

**SUPPLEMENTARY INFORMATION:**

**Background**

The LLNA is a reduction and refinement alternative test method for skin sensitization testing because it reduces the number of animals needed and can substantially reduce or avoid pain and distress compared to traditional guinea pig testing methods for sensitization. The LLNA was the first alternative test method evaluated and recommended by ICCVAM (NIH Publication No. 99–4494, available at: *http://iccvam.niehs.nih.gov/docs/immunotox_docs/llna/llnarep.pdf*). Based on the recommendations of ICCVAM and an independent scientific peer review panel, U.S. and international regulatory authorities have accepted the LLNA as an alternative to the guinea pig maximization test and Buehler test for assessing allergic contact dermatitis (ISO 2002; OECD 2002; EPA 2003). This review will evaluate the potential for broader use of the LLNA for regulatory testing of chemicals and products for allergic contact dermatitis potential, enabling further reduction and refinement (less pain and suffering) of animal use for this purpose. In January 2007, the CPSC submitted a nomination requesting that NICEATM and ICCVAM assess the validation status of (1) the LLNA as a stand-alone assay for potency determination for hazard classification purposes; (2) modified LLNA protocols; (3) the LLNA limit test; (4) the use of the LLNA to test mixtures, aqueous solutions, and metals; and (5) the applicability domain for the LLNA. In June 2007, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) endorsed these activities as high priorities for ICCVAM. NICEATM on behalf of ICCVAM also sought input from the public on these activities (**Federal Register**: Vol. 72, No. 95, pages 27815–27817, May 17, 2007). After considering these inputs, ICCVAM endorsed these activities as high priorities. ICCVAM is also developing performance standards to facilitate evaluation of modified LLNA protocols compared to the traditional LLNA. Although ICCVAM has routinely developed performance standards for test methods since 2003, they were not developed as part of the ICCVAM evaluation of the LLNA in 1998. These draft performance standards for the LLNA were made public and comments were requested via the **Federal Register** (Vol. 72, No. 176, pages 52130–52131, Sept. 12, 2007). The May 2007 **Federal Register** notice requested data from studies using the LLNA or modified versions of the LLNA.

Drawing on the submitted data and literature sources, ICCVAM and NICEATM drafted background review documents for each of the modifications and new applications of the LLNA. ICCVAM has also developed draft test method recommendations regarding the proposed usefulness, limitations, and validation status of these test methods. ICCVAM will convene an independent scientific panel to peer review the draft background review documents for the test methods and determine whether the data and analyses in the draft documents support the draft ICCVAM test method recommendations. The panel will also be asked to comment on the adequacy of the revised draft performance standards, proposed future studies, draft standardized test method protocols, and recommended reference substances. NICEATM will ask the panel to consider all available information, including the scientific studies cited in the draft review documents, public comments, and any new information identified during the peer review, for developing their conclusions and recommendations.

**Peer Review Panel Meeting**

The purpose of this meeting is to conduct a scientific peer review of the revised draft performance standards and an evaluation of modifications and new applications for the LLNA. The LLNA is an alternative test method that can be used to determine the allergic contact dermatitis potential of chemicals and products. The panel will review the following:

- The LLNA as a stand-alone assay for potency determination for hazard classification purposes
- Modified LLNA protocols
- The LLNA limit test
- The use of the LLNA to test mixtures, aqueous solutions, and metals (applicability domain for the LLNA)
- The use of the LLNA to determine potency (potential for causing allergic contact dermatitis).

The panel will consider the draft background review documents for each of these methods and evaluate the extent that established validation and acceptance criteria are appropriately addressed for each test method (as described in the ICCVAM document, *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 No. 97–981, available at *http://iccvam.niehs.nih.gov/docs/about_docs/validate.pdf*). The panel will then comment on the extent to which the draft ICCVAM recommendations are supported by the information provided in the background review document for each topic. It is anticipated that the panel will address the topics in the following order:

1. The LLNA limit test.
2. The applicability domain of the LLNA including its suitability for mixtures, aqueous solutions, and metals.
3. The LLNA as a stand-alone assay for potency determination for hazard classification.
4. The revised draft performance standards for the LLNA.
5. The modified LLNA test method protocols using non-radioactive materials.

Additional information about the meeting, including a roster of the panel members and the draft agenda, will be made available two weeks prior to the meeting on the NICEATM-ICCVAM Web site (*http://iccvam.niehs.nih.gov*). This information will also be available after that date by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT** above).

**Attendance and Registration**

This public meeting will take place March 4–6, 2008, at the CPSC Headquarters, Bethesda Towers Bldg., 4330 East West Highway, Bethesda, MD (an area map, driving directions, and CPSC contact information are available at *http://www.cpsc.gov/about/contact.html*). The meeting will begin at 8:30 a.m. and is scheduled to conclude at approximately 5 p.m. each day, although adjournment on March 6 may occur earlier or later depending upon the time needed for the expert panel to complete its work. It is also possible that the panel may conclude its deliberations on March 5 and not need to meet on March 6. Persons needing special assistance in order to attend, such as sign language interpretation or other reasonable accommodation, should contact 919–541–2475 (voice), 919–541–4644 TTY (text telephone, through the Federal TTY Relay System at 800–877–8339), or e-mail *niehsoeeo@niehs.nih.gov.* Requests should be made at least seven days in advance of the event.

**Availability of the Draft Background Review Documents and Draft ICCVAM Recommendations**

NICEATM prepared draft background review documents on each of these modifications or applications of the LLNA that describe the current validation status of the modified test methods and applications and contain all of the data and analyses supporting this proposed validation status. The draft background review documents, draft ICCVAM test method recommendations, draft test method protocols, and revised draft test method performance standards are available from the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm*) or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT** above).

**Request for Public Comments**

NICEATM invites the submission of written comments on the draft background review documents, draft ICCVAM test method recommendations, draft test method protocols, and revised draft test method performance standards. Written comments should be submitted preferably electronically via the NICEATM–ICCVAM Web site or by e-mail (*niceatm@niehs.nih.gov*); the deadline for submission of written comments is February 22, 2008. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). Written comments may also be sent by mail, fax, or e-mail to Dr. William Stokes (see **FOR FURTHER INFORMATION CONTACT** above). All comments received will be placed on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*) and identified by the individual's name and affiliation or sponsoring organization (if applicable). Comments will also be sent to the panel and ICCVAM agency representatives and made available at the meeting.

This meeting is open to the public, and time will be provided for the presentation of oral comments by the public at designated times during the peer review. Members of the public who wish to present oral statements at the meeting should contact NICEATM (see **FOR FURTHER INFORMATION CONTACT** above) no later than February 20, 2008, and provide contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). Up to seven minutes will be allotted per speaker, one speaker per organization. Persons registering to make comments are asked to provide NICEATM a written copy of their statement by February 27, 2008, so that copies can be distributed to the panel prior to the meeting. If this is not possible, please bring 40 copies of your comments to the meeting for distribution and to supplement the record. Written statements can supplement and expand the oral presentation.

Summary minutes and the panel's final report will be available following the meeting on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*). ICCVAM will consider the panel's conclusions and recommendations and any public comments received when finalizing their test method recommendations and performance standards for these methods.

**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, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) establishes ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers 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 is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov.*

**References**

EPA. 2003. EPA OPPTS 870.2600 Test Guideline—Skin Sensitization. Available: *http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870–2600.pdf.*

ISO. 2002. ISO 10993–10 Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity. Geneva: International Organization for Standardization.

OECD. 2002. OECD Guideline for the Testing of Chemicals—Test Guideline 429: Skin Sensitization: Local Lymph Node Assay (adopted 24 April 2002). Paris: Organisation for Economic Co-operation and Development.

Dated: December 19, 2007.

**Samuel H. Wilson,**

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

[FR Doc. E7–25553 Filed 1–7–08; 2:42 pm]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2007–0197]**

### Area Maritime Security Advisory Committee Detroit; Vacancies

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for applications.

**SUMMARY:** The Coast Guard seeks applications for membership in the Area Maritime Security Committee (AMSC) Detroit. The Committee assists the Captain of the Port, Detroit, in developing, reviewing, and updating the