Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: September 24, 2009.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Test Method Evaluation Report: The Reduced Murine Local Lymph Node Assay, an Alternative Test Method Using Fewer Animals To Assess the Allergic Contact Dermatitis Potential of Chemicals and Products; Availability of ICCVAM Recommended Murine Local Lymph Node Assay Performance Standards; Notice of Transmittal to Federal Agencies of ICCVAM Test Method Recommendations for the Reduced Murine Local Lymph Node Assay, Updated Murine Local Lymph Node Assay Test Method Protocol, and Murine Local Lymph Node Assay Test Method Performance Standards

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

ACTION: Availability of ICCVAM Test Method Evaluation Report (TMER) and Recommended Test Method Performance Standards; Notice of Transmittal.

SUMMARY: NICEATM announces availability of the *ICCVAM Test Method Evaluation Report: The Reduced Murine Local Lymph Node Assay: An Alternative Test Method Using Fewer Animals to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication 09–6439). The TMER provides ICCVAM's evaluation and recommendations for the reduced Murine Local Lymph Node Assay (rLLNA) test method as a reduction alternative that uses fewer animals compared to the traditional Murine Local Lymph Node Assay (LLNA) for assessing the potential of test substances to cause allergic contact dermatitis (ACD). The report includes ICCVAM's recommendations on (a) the usefulness and limitations of the rLLNA, (b) an updated ICCVAM LLNA test method protocol, which includes the procedures for conducting the rLLNA, (c) future studies to further characterize the usefulness and limitations of the rLLNA, and (d) rLLNA test method performance standards. The TMER includes the report of an international independent scientific peer review panel (hereafter, Panel) and the final rLLNA background review document (BRD). The BRD provides the data and analyses used to evaluate the current validation status of the rLLNA test method for assessing the ACD potential of chemicals and products. ICCVAM concluded that the scientific validity of the rLLNA has been adequately evaluated and that the performance of the rLLNA, when conducted in accordance with the ICCVAM-recommended LLNA test method protocol, is sufficient to distinguish between skin sensitizers and non-sensitizers. ICCVAM also concluded that the rLLNA would reduce animal use by 40% for each test compared to the traditional, multi-dose LLNA. Accordingly, ICCVAM recommends that the rLLNA test method should be routinely considered before conducting the traditional, multi-dose LLNA, and used where appropriate as the initial test to determine the potential of chemicals and products to produce ACD. For testing situations that require dose-response information, rLLNA-positive substances will need to be tested with the traditional multi-dose LLNA. This testing should be done using the updated ICCVAM-recommended test method protocol, which reduces animal use by 20% compared to the original ICCVAM-recommended test method protocol by decreasing the minimum number of animals per dose group from five to four.

NICEATM also announces availability of the *ICCVAM Recommended Performance Standards: Murine Local Lymph Node Assay* (NIH Publication 09–7357). The ICCVAM recommends that LLNA test method performance standards can be used to efficiently evaluate the validity of modified versions of the LLNA that are mechanistically and functionally similar to the traditional LLNA. The traditional LLNA test method is the reference test method used as the basis for establishing the LLNA performance standards. The performance standards specify the essential test method components that must be included in a modified LLNA in order to use the performance standards to evaluate the validity of the modified test method. The performance standards also specify a minimum list of reference substances to evaluate the accuracy and reliability of the modified test method, and the accuracy and reliability values that must be achieved in order for the modified test method to be considered equal to or better than the traditional LLNA.

Electronic copies of the ICCVAM rLLNA TMER and the report on ICCVAM-recommended LLNA performance standards are available from the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov* or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT**). The two reports have been forwarded to U.S. Federal agencies for regulatory and other acceptance considerations, where applicable. Responses will be posted on the NICEATM–ICCVAM website as they are received.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Consumer Product Safety Commission (CPSC) nominated several new versions and applications of the LLNA to ICCVAM in 2007 for evaluation of their scientific validity (*http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf*). The nomination requested that ICCVAM assess the validation status of: (1) the LLNA limit dose procedure (*i.e.,* the rLLNA); (2) three modified LLNA test method protocols that do not require the use of radioactive materials; (3) the use of the LLNA to test mixtures, aqueous solutions, and metals (applicability domain for the LLNA); and (4) the use of the LLNA to determine ACD potency categories for hazard classification. NICEATM published a **Federal Register** notice (72 FR 27815) requesting public comments on the appropriateness and relative priority of the CPSC-nominated LLNA activities, the development of test method performance standards for the LLNA, the nomination of scientists to serve on the Panel, and the submission of data from LLNA testing that related to the CPSC-nominated LLNA activities, as well as corresponding data from human and other animal studies. After considering public comments and comments from the Scientific Advisory Committee on Alternative Toxicological

Methods (SACATM), ICCVAM unanimously endorsed the nomination with a high priority. ICCVAM and NICEATM began evaluation activities and also initiated development of proposed test method performance standards for the LLNA since these had not previously been developed (*http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm*). NICEATM and ICCVAM compiled a comprehensive draft BRD on the rLLNA test method and a draft test method performance standards document for the LLNA and released them for public comment in January 2008 (73 FR 1360).

NICEATM and ICCVAM convened the Panel at a meeting on March 4–6, 2008, to review the draft BRDs and evaluate the validation status of the proposed test methods and applications. The Panel also reviewed the extent that the information contained in the draft BRDs supported draft ICCVAM test method recommendations for test method uses and limitations, updated standardized test method protocols, and proposed future studies. The Panel reviewed the draft ICCVAM LLNA test method performance standards for their adequacy for assessing the accuracy and reliability of test method protocols that are based on similar scientific principles and that measure the same biological effect as the traditional LLNA. The Panel considered public comments made at the meeting as well as public comments submitted in advance of the meeting, before concluding their deliberations. The Panel's report was made available in May 2008 (73 FR 29136) for public comment. The draft ICCVAM BRDs, draft ICCVAM test method recommendations, draft ICCVAM LLNA test method performance standards, the Panel's report, and all public comments were made available to the SACATM for comment on June 18–19, 2008 (73 FR 25754).

ICCVAM considered the Panel's report, all public comments, and SACATM comments in finalizing its recommendations for the rLLNA, the updated LLNA test method protocol, and LLNA test method performance standards. ICCVAM has forwarded its test method recommendations to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3(e)(4)). Agency responses to the ICCVAM test method recommendations will be made available on the NICEATM–ICCVAM Web site as they are received.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate 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 established 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 U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (*http://www.iccvam.niehs.nih.gov).*

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily-mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

Dated: September 22, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charter for the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the U.S. Department of Health and Human Services is hereby announcing that the charter for the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020 (Healthy People 2020 Advisory Committee; HPAC) has been renewed.

FOR FURTHER INFORMATION CONTACT: Emmeline Ochiai, Executive Secretary, Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020, Department of Health and Human Services, Office of Public Health and Science, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852; Telephone: (240) 453–8259; Fax (240) 453–8281. Additional information is available on the Internet at *http://www.healthypeople.gov*.

SUPPLEMENTARY INFORMATION: Every ten years, through the Healthy People initiative, the U.S. Department of Health and Human Services (HHS) leverages scientific insights and lessons from the past decade, along with the new knowledge of current data, trends, and innovations to develop the next iteration of the national health promotion and disease prevention objectives. Healthy People provides science-based, ten-year national objectives for promoting health and preventing disease. Since 1980, Healthy People has set and monitored national health objectives to meet a broad range of health needs, encourage collaborations across sectors, guide individuals toward making informed health decisions, and measure the impact of our prevention and health promotion activities. *Healthy People 2020* will reflect assessment of major risks to health and wellness, changing public health priorities, and emerging technologies related to our nation's health preparedness and prevention.

The Committee will continue to provide advice and consultation to the Secretary of Health and Human Services for developing and implementing the next iteration of the national health promotion and disease prevention goals and objectives and provide recommendations for initiatives to occur during the implementation phase of the goals and objectives. HHS will use the recommendations to form the development of the national health promotion and disease prevention objectives for 2020 and the process for implementing the objectives. The intent is to develop and launch objectives designed to improve the health status and reduce health risks for Americans by the year 2020. Renewal of the HPAC charter provides authorization for the Committee to operate until September 4,