

Elizabeth Doyle, PhD, Chief, Human Health Risk Assessment Branch, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

Isabel Garcia, DDS, MPH, Acting Director, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

Barbara Gooch, DMD, MPH, Acting Associate Director for Science, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jesse Goodman, MD, MPH, Chief Scientist and Deputy Commissioner for Science and Public Health, Food and Drug Administration, U.S. Department of Health and Human Services.

J. Nadine Gracia, MD, MSCE, Chief Medical Officer, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Susan O. Griffin, PhD, Health Economist, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Laurence Grummer-Strawn, PhD, Chief, Maternal and Child Nutrition Branch, Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Jay Hirschman, MPH, CNS, Director, Special Nutrition Staff, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture.

Frederick Hyman, DDS, MPH, Division of Dermatology and Dental Products, Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services.

Timothy Iafolla, DMD, MPH, Office of Science and Policy Analysis, National Institute of Dental and Craniofacial Research, National Institutes of Health, U.S. Department of Health and Human Services.

William Kohn, DDS, Director, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

Richard Manski, DDS, MBA, PhD, Senior Scholar, Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Benson Silverman, MD, Staff Director, Infant Formula and Medical Foods, Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services.

Thomas Sinks, PhD, Deputy Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

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BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on January 25, 2011 from 1:15 p.m. to 3 p.m. ET. The agenda is subject to change as priorities dictate.

ADDRESSES: Department of Health and Human Services; Hubert H. Humphrey Building, Room 800; 200 Independence Avenue, SW., Washington, DC 20201. To attend by teleconference, call 1-866-395-4129, pass-code "ASPR." Please call 15 minutes prior to the beginning of the conference call to facilitate attendance. Pre-registration is required for public attendance. Individuals who wish to attend the meeting in person should send an email to NBSB@HHS.GOV with "NBSB Registration" in the subject line.

FOR FURTHER INFORMATION CONTACT: E-mail: NBSB@HHS.GOV.

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

Background: A portion of this public meeting will be dedicated to swearing in the six new voting members who will replace the members whose 3-year terms expired on December 31, 2010. The Board will be asked to consider the various components of a science response to disasters. Subsequent agenda topics will be added as priorities dictate.

Availability of Materials: The meeting agenda and materials will be posted on the NBSB Web site at <http://www.phe.gov/Preparedness/legal/boards/nbsb/Pages/default.aspx> prior to the meeting.

Procedures for Providing Public Input: Any member of the public providing oral comments at the meeting must sign in at the registration desk and provide his/her name, address, and affiliation. All written comments must be received prior to January 18, 2011 and should be sent by e-mail to NBSB@HHS.GOV with "NBSB Public Comment" as the subject line. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should e-mail NBSB@HHS.GOV.

Dated: January 7, 2011.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

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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); Federal Agency Responses to Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Recommendations on Two Nonradioactive Versions of the Murine Local Lymph Node Assay (LLNA) for Assessing Allergic Contact Dermatitis (ACD) Hazard Potential of Chemicals and Products, and Expanded Uses of the LLNA for Pesticide Formulations and Other Products; Notice of Availability

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

ACTION: Notice of Availability.

SUMMARY: U.S. Federal agency responses to ICCVAM test method recommendations on two nonradioactive versions of the LLNA for assessing the ACD hazard potential of chemicals and products and for expanded uses of the LLNA for pesticide formulations and other products are now available on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm>. ICCVAM recommended the nonradioactive LLNA: 5-bromo-2-deoxyuridine-enzyme-linked immunosorbent assay

(BrdU-ELISA) and LLNA: Daicel Adenosine Triphosphate (DA), and expanded uses for the LLNA. In accordance with the ICCVAM Authorization Act (42 U.S.C. 285l-3(e)(4)), ICCVAM forwarded recommendations to Federal agencies and made these recommendations available to the public (75 FR 37443). Agencies have now notified ICCVAM in writing of their findings and ICCVAM is making these responses available to the public.

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

In 1999, ICCVAM recommended the LLNA as a valid safety test for assessing the ACD hazard potential of many chemicals and products (NIH Publication No. 99-4494; available at http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel98.htm). ICCVAM also concluded that the LLNA, when used as an alternative method to the guinea pig maximization test (GPMT) or the Buehler test (BT), could also significantly reduce animal use and improve animal welfare. Based on this evaluation, the U.S. Environmental Protection Agency (EPA 2003), the U.S. Food and Drug Administration, and the U.S. Consumer Product Safety Commission (CPSC) subsequently accepted the method as a valid substitute for the GPMT and BT (http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel98.htm). The Organisation for Economic Co-operation and Development (OECD) subsequently adopted the LLNA in 2002 as international OECD Test Guideline 429 (OECD, 2002). The International Organization for Standardization (ISO) adopted the LLNA as ISO standard 10993-10 in 2002 (ISO, 2002).

ICCVAM recommended an updated LLNA test method protocol in 2009 that further reduced animal use for each safety test by 20-40% (ICCVAM, 2009). Federal agencies endorsed this updated protocol (75 FR 25866). OECD Test Guideline 429 was subsequently updated in 2010 to incorporate the updated revisions (OECD, 2010a). The ISO standard was also updated in 2010 (ISO, 2010).

Compared to the LLNA, the LLNA: BrdU-ELISA and LLNA: DA do not use

radioactive reagents and therefore provide additional advantages in terms of reduced hazardous waste disposal and broader availability for use by laboratories that cannot use radioactive reagents. ICCVAM concludes that the accuracy and reliability of the LLNA: BrdU-ELISA and LLNA: DA support their use to determine whether substances have the potential to cause ACD. The protocols also include reduced LLNA: BrdU-ELISA and LLNA: DA procedures that should always be considered and used where determined appropriate because they can further reduce animal use by 40% compared to multi-dose procedures. The ICCVAM evaluation and complete recommendations for the LLNA: BrdU-ELISA and LLNA: DA are provided in the *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: BrdU-ELISA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication No. 10-7552, available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna-ELISA/TMER.htm>) and the *ICCVAM Test Method Evaluation Report on the Murine Local Lymph Node Assay: DA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication No. 10-7551, available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna-DA/TMER.htm>). The OECD subsequently adopted the LLNA: BrdU-ELISA and LLNA: DA as international test guidelines (OECD, 2010b, 2010c).

ICCVAM also concluded that available data support the use of the LLNA for safety testing of a broader range of chemicals and products, including pesticide formulations, metals with the exception of nickel, substances in aqueous solutions, and other chemicals and products, unless there are unique physicochemical properties associated with these materials that may interfere with the accuracy of the LLNA. Aqueous solutions should be tested in an appropriate vehicle that maintains sufficient contact of the test article with the skin. The ICCVAM evaluation and complete recommendations for expanded uses of the LLNA are provided in *ICCVAM Test Method Evaluation Report on Using the Murine Local Lymph Node Assay for Testing Pesticide Formulations, Metals, Substances in Aqueous Solutions, and Other Products* (NIH Publication No. 10-7512, available at <http://iccvam.niehs.nih.gov/methods/immunotox/LLNA-app/TMER.htm>).

ICCVAM evaluated the new versions and applications of the LLNA in response to a 2007 nomination from CPSC (http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf). The nomination requested that ICCVAM assess (1) the validation status of the LLNA limit dose procedure (*i.e.*, the reduced LLNA); (2) 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; and (4) the use of the LLNA as a stand-alone assay to determine ACD potency categories for hazard classification. ICCVAM recommendations on an updated LLNA test method protocol that included the reduced LLNA were communicated to Federal agencies and each of the 15 ICCVAM agencies concurred with the ICCVAM recommendations for the reduced LLNA. ICCVAM has completed the evaluation of the LLNA for its validity for potency categorization of chemicals causing ACD in humans. Final ICCVAM recommendations will be forwarded to Federal agencies in 2011.

Agency Responses to ICCVAM Recommendations

In June 2010, ICCVAM forwarded final test method recommendations for the LLNA BrdU-ELISA, LLNA: DA and the expanded uses of the LLNA to U.S. Federal agencies for consideration (74 FR 50212), in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3(e)(4)). The Act requires agencies to review ICCVAM test method recommendations and notify ICCVAM in writing of their findings no later than 180 days after receipt of recommendations. The Act also requires ICCVAM to make ICCVAM recommendations and agency responses available to the public. Agency responses are to include identification of relevant test methods for which the ICCVAM test method recommendations may be added or substituted, and indicate any revisions or planned revisions to existing guidelines, guidances, or regulations to be made in response to these recommendations.

Federal agency responses include acceptance decisions and agreement with the test method recommendations for the LLNA: BrdU-ELISA, LLNA: DA and the expanded uses of the LLNA. Several agencies also indicated that they would communicate the ICCVAM recommendations to stakeholders and encourage their appropriate use. Agency responses are available at <http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm>.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM (42 U.S.C. 285l-3(a)). NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitation of new, revised, and alternative test methods. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

References

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Dated: January 5, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Connecting Primary Care Practices with Hard-to-Reach Adolescent Populations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by March 14, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION: