

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS); Notice of Meeting to Review the Murine Local Lymph Node Assay (LLNA) as an Alternative Test Method for Contact Hypersensitivity; Request for Comments

SUMMARY: Pursuant to Public Law 103-43, notice is hereby given of a public meeting sponsored by the NIEHS and the National Toxicology Program (NTP), 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 (NTP Center). The agenda topic is the scientific peer review of the murine local lymph node assay (LLNA), which is proposed as an alternative toxicological test method for assessing contact hypersensitivity (allergic contact dermatitis) potential of chemicals and products. The meeting will be held on September 17, 1998, at the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, Maryland. The meeting will take place from 8:30 a.m. to 4:30 p.m. and is open to the public.

Background

Public Law 103-43 directed the NIEHS to develop and validate alternative methods that can reduce or eliminate the use of animals in acute or chronic toxicity testing, establish criteria for the validation and regulatory acceptance of alternative testing methods, and recommend a process through which scientifically validated alternative methods can be accepted for regulatory use. Criteria and processes for validation and regulatory acceptance were developed in conjunction with 13 other Federal agencies and programs with broad input from the public. These are described in the 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 97-3981, March 1997, which is available on the internet at <http://ntp-server.niehs.nih.gov/htdocs/ICCVAM/ICCVAM.htm>. An interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was subsequently established in a collaborative effort by NIEHS and 13 other Federal regulatory and research

agencies and programs. 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 and organizations are participating in this effort:

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

The LLNA was proposed to the ICCVAM for consideration as a stand-alone test to identify chemicals that have a potential to cause contact hypersensitivity (allergic contact dermatitis). An ICCVAM Immunotoxicity Working Group composed of Federal employees determined that there was sufficient information available to merit an independent scientific peer review of the LLNA test method. Peer review has been determined to be an essential prerequisite for consideration of a method for regulatory acceptance. The peer review panel will be charged with developing a scientific consensus on the usefulness of the test method to generate information for various human health risk assessment purposes. Following evaluation at this peer review meeting, the proposed test method and results of the peer review will be forwarded by ICCVAM to Federal agencies for consideration. Federal agencies will determine the regulatory acceptability of a method according to their mandates.

Agenda

There will be a brief orientation on the ICCVAM and the ICCVAM review process, followed by peer review of the proposed LLNA test method and supporting information. The peer

review panel will discuss the usefulness of the LLNA as an alternative to test methods currently accepted by government regulatory authorities for the assessment of the contact hypersensitivity potential of chemicals and products. Copies of the proposed LLNA Test Method Protocol and supporting documentation may be obtained from the NTP Center for the Evaluation of Alternative Toxicological Methods, MD EC-17, P.O. Box 12233, Research Triangle Park, NC, 27709 (919-541-3398), FAX (919-541-0947), e-mail: ICCVAM@niehs.nih.gov. The LLNA test method documents and copies of written public comments can also be viewed at the Documents Management Branch, Food and Drug Administration, 5630 Fishers Lane, Room 1081, Rockville, MD, 20852 on Monday through Friday from 9:00 a.m. to 4:00 p.m.

Public Comment

The NTP Center invites the submission of written comments on the proposed LLNA test method, and other available information regarding the usefulness of the LLNA, including information about completed, ongoing, or planned studies. Written comments and additional information should be sent by mail, fax, or e-mail to the NTP Center at the address listed above by August 14th. Written comments will be made available to the peer review panel members, ICCVAM agency representatives and experts, and will be made available for attendees at the meeting. Members of the public who wish to present oral statements at the meeting should also contact the NTP Center as soon as possible, but not later than September 11, 1998. Speakers will be assigned on a first-come, first-serve basis and will be limited to a maximum of five minutes in presentation length. Written comments accompanying the oral statement should be submitted in advance so that copies can be made and distributed to the peer panel members.

The NTP Center will furnish an agenda and a roster of peer review panel members just prior to the meeting. Summary minutes and a final report of the LLNA peer review meeting will be available subsequent to the meeting upon request to the Center. Persons needing special assistance, such as sign language interpretation or other special accommodations should contact the NTP Center as described above.

Dated: June 30, 1998.
Kenneth Olden,
Director, National Toxicology Program.
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