[Federal Register: March 23, 1999 (Volume 64, Number 55)]
[Notices]
[Page 14006-14007]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23mr99-99]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS); The Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals/Compounds, Report Now Available

SUMMARY: The report entitled ``The Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals/Compounds," NIH Publication 99-4494, is now available and may be obtained as described in this notice. The report describes the results of an independent peer review evaluation of the validation status of the Local Lymph Node Assay (LLNA) that was conducted on September 17, 1998 (Federal Register 63 FR 37405-6, July 10, 1998). The (LLNA) was proposed as an alternative toxicological test method for assessing the allergic contact dermatitis (contact hypersensitivity) potential of chemicals and products. The review was coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The review was sponsored by the National Institute of Environmental Health Sciences and the NTP.

Background

Pub. L. 103-43 directed the NEIHS 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 14 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.html. ICCVAM was subsequently establihsed 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 ICCVAM for consideration as a stand-alone test to identify chemicals that have a potential to cause allergic contact dermatitis. The ICCVAM determined that there was sufficient information available to merit an independent scientific peer review evaluation of the LLNA test method. Peer review is an essential prerequisite

[[Page 14007]]

for consideration of a method for regulatory acceptance. The peer review panel was charged with developing a scientific consensus on the usefulness and limitations of the test method. The peer review panel concluded that the LLNA is a valid alternative to currently accepted guinea pig test methods for the assessment of allergic contact dermatitis when the test method is conducted in accordance with peer review panel recommendations. The panel also concluded that the LLNA offers animal welfare advantages compared to conventional guinea pig methods in that it involves less pain and distress, and fewer animals may be required. The peer review panel's report has been forwarded to Federal agencies for their determination of the regulatory acceptability and applicability of the test method according to their statutory mandates.

Summary of the Report

The report contains 212 pages and includes the results of the independent peer review evaluation and supporting documentation, including the original test method submission, supporting data evaluations conducted by NICEATM, and a proposed protocol that incorporates the recommendations of the peer review panel.

Obtaining the Report

To receive a copy of the report, please contact NICEATM at PO Box 12233, MD EC-17, Research Triangle Park, NC 27709 (mail), 919-541-3398 (phone), 919-541-0947 (fax), or iccvam@niehs.nih.gov (email). The report is also available on the ICCVAM/NICEATM website at http://

iccvam.niehs.nih.gov/llnarep.htm.

Dated: March 11, 1999.
Samuel H. Wilson,
Deputy Director, National Institutes of Environmental Health Sciences.
[FR Doc. 99-6953 Filed 3-22-99; 8:45 am]
BILLING CODE 4140-01-M