DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Peer Review Panel Report on Five In Vitro Pyrogen Test Methods: Availability and Request for Public Comments

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

ACTION: Request for comments.

SUMMARY: NICEATM in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) convened an independent scientific peer review panel meeting on February 6, 2007, to evaluate the validation status of five in vitro pyrogen test methods proposed as replacements for the Rabbit Pyrogen Test (RPT). The peer review panel (''the Panel'') report from this meeting is now available. The report contains (1) the Panel's evaluation of the validation status of the methods and (2) the Panel's comments and conclusions on draft ICCVAM test method recommendations. NICEATM invites public comment on the Panel's report. The report is available on the NICEATM/ICCVAM Web site at (*http://iccvam.niehs.nih.gov/methods/pyrogen/pyrogen.htm*) or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT** below).

DATES: Written comments on the Panel report should be received by June 25, 2007.

ADDRESSES: Comments should preferably be submitted electronically via the NICEATM/ICCVAM Web site: *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm*. Comments can also be submitted by e-mail to *niceatm@niehs.nih.gov*. Written comments can be sent by mail or fax to Dr. William S. Stokes, NICEATM Director, NIH/NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (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.

FOR FURTHER INFORMATION CONTACT: Other correspondence should be directed to Dr. William S. Stokes, NICEATM Director (919–541–2384 or *niceatm@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION

Background

The European Centre for the Validation of Alternative Methods (ECVAM) submitted five *in vitro* pyrogen test methods to ICCVAM for evaluation in 2006. The proposed test methods include:

1. The Human Whole Blood (WB)/IL–1 *In Vitro* Pyrogen Test: Application of Cryopreserved Human WB
2. The Monocytoid Cell Line Mono Mac 6 (MM6)/IL–6 *In Vitro* Pyrogen Test
3. The Human PBMC/IL–6 *In Vitro* Pyrogen Test
4. The Human WB/IL–1 *In Vitro* Pyrogen Test
5. The Human WB/IL–6 *In Vitro* Pyrogen Test

These test methods are based on the measurement of proinflammatory cytokines released from either fresh or cryopreserved human blood cells or a human monocytoid line in response to the presence of Gram-negative endotoxin in parenteral pharmaceuticals. NICEATM and ICCVAM prepared a comprehensive background review document (BRD) that included the available data for the five test methods and a separate document containing ICCVAM test method recommendations. At the peer review meeting, the Panel reviewed the BRD and evaluated the extent to which the ICCVAM criteria for validation and acceptance had been adequately addressed for the intended purpose of these test methods. The Panel also provided comments on the ICCVAM draft test method recommendations regarding the proposed usefulness and limitations, standardized protocols, performance standards, and future studies. The Panel's conclusions and recommendations on the five in vitro pyrogen test methods are described in the *Peer Review Panel Final Report: Five In Vitro Pyrogen Test Methods* (available at: *http://iccvam.niehs.nih.gov/methods/pyrogen/pyrogen.htm*). The draft BRD and the draft test method recommendations are available at *http://iccvam.niehs.nih.gov/methods/pyrogen/pyrogen.htm*.

Request for Comments

NICEATM invites the submission of written comments on the Panel's report. When submitting written comments please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, email, and sponsoring organization, if applicable). All comments received by the deadline listed above will be placed on the NICEATM/ICCVAM Web site (*http://ntp-apps.niehs.nih.gov/iccvampb/searchPubCom.cfm*) and made available to ICCVAM. In addition, there will be an opportunity for oral public comments on the Panel's report during a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) scheduled for June 12, 2007. Information concerning the SACATM meeting will be published in a separate **Federal Register** notice and available on the SACATM website: (*http://ntp.niehs.nih.gov/go/7441*). Any written comments on the Panel report received prior to June 7, 2007, will be distributed to SACATM.

ICCVAM will consider the Panel report along with the SACATM and public comments as it finalizes recommendations for the five *in vitro* pyrogen test methods. An ICCVAM test method evaluation report, which includes the ICCVAM final recommendations, will be forwarded to appropriate federal agencies for their consideration. This report will also be available to the public on the NICEATM/ICCVAM Web site and by request from NICEATM.

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 scientific validation and regulatory acceptance of toxicological test methods that more accurately assess safety and hazards of chemicals and products and that refine, reduce, and 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 can be found at the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov*).

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: April 30, 2007.

Samuel H. Wilson,

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

[FR Doc. E7–8896 Filed 5–8–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Request for Data on the Use of Topical Anesthetics and Systemic Analgesics for In Vivo Eye Irritation Testing

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

ACTION: Request for data on the use of topical anesthetics and systemic analgesics for in vivo ocular irritation testing.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM request the submission of data and information on the use of topical anesthetics and systemic analgesics for alleviating pain and distress in rabbits during eye irritation testing. They also request the submission of information about other procedures and strategies that may reduce or eliminate pain and distress associated with *in vivo* eye irritation methods.

DATES: Data should be received by June 25, 2007.

ADDRESSES: Data should be sent by mail, fax, or e-mail to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (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.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, NICEATM Director, (phone) 919–541–2384 or *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION

Background

The U.S. Environmental Protection Agency (EPA) nominated to ICCVAM several activities relevant to reducing, replacing, or refining the use of rabbits in the current *in vivo* eye irritation test method (**Federal Register** Vol. 69, No. 57, pages 13859–13861, March 24, 2004). One activity is to review ways to alleviate pain and suffering that might arise from current *in vivo* eye irritation testing. ICCVAM endorsed this activity with a high priority and recommended that NICEATM review the data currently available on the use of topical anesthetics and/or systemic analgesics to reduce animal pain and distress.

As part of this review, NICEATM requests the submission of data from completed studies on the use of topical anesthetics and/or systemic analgesics for *in vivo* ocular irritancy testing. These data will be used to evaluate the validation status of the use of topical anesthetics and/or analgesics to reduce pain and distress for *in vivo* testing situations. ICCVAM and NICEATM also request the submission of information and data from *in vivo* methods, procedures, and/or strategies that may reduce or eliminate the pain and suffering associated with current *in vivo* eye irritation 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. 285*l*–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. Additional information about NICEATM and ICCVAM can be found at the following Web site: *http://iccvam.niehs.nih.gov.*

Dated: April 30, 2007.

Samuel H. Wilson,

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

[FR Doc. E7–8898 Filed 5–8–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Purpose of Notice: Availability of Funding Opportunity Announcement

Funding Opportunity Title/Program Name: Aging and Disability Resource Center Initiative: Integrating Access to Long-Term Care.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2007–AoA–DR–0707.

Statutory Authority: The Older Americans Act of 2006, Public Law 109–365.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.048, Title IV and Title II, Discretionary Projects.

Dates: The deadline date for the submission of applications is June 29, 2007.

I. Funding Opportunity Description

In FY 2003, the Administration on Aging (AoA) and the Centers for Medicare & Medicaid Services (CMS) formed a historic partnership to launch the Aging and Disability Resource Center (ADRC) demonstration grant initiative. The goal of the ADRC program is to empower individuals to make informed choices and to streamline access to long term support services. AoA and CMS share a vision to have Resource Centers in every community serving as highly visible and trusted places where people of all ages can turn for information on the full range of long term support options and a single point of entry to public long term support programs and benefits. ADRCs are a resource for both public and private-pay individuals. They serve older adults, younger individuals with disabilities, family caregivers, as well as persons planning for future long term support needs. ADRCs are also a resource for health and long term support professionals and others who provide services to older adults and to people with disabilities. Since FY 2003, 43 states have received three year grants from AoA and CMS to design and implement ADRC demonstrations serving the elderly and at least one other target population of adults with disabilities in at least one community. An ADRC Program Announcement published in FY 2003 resulted in the funding of twelve states that year with an additional twelve states funded to develop ADRC programs in FY 2004. Nineteen additional states were funded to develop ADRC programs based on a Program Announcement published in