Application of GLPs to *In Vitro* Test Methods
- ICCVAM/ECVAM Proposal for Development of International Guidance
- ECVAM Guidelines for Good Cell Culture Practices
- Public Comments

Minimum Performance Standards for Test Methods
- MPS for In Vitro Corrosivity Methods
- Public Comments

In Vitro Endocrine Binding and Transcriptional Activation Assays: Minimum Procedural Standards and Reference Chemicals
- Public Comments

12:05 p.m.—Lunch (on your own)

1 p.m.—Overview of ILSI/HESI Work Group's Activities on Identification of Biomarkers of Toxicity and Summary of First Meeting

Validation of Genetically Modified Mouse Models
- Public Comments

2:45 p.m.—Adjourn

Public Comment Welcome

- Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the NTP Executive Secretary (contact information above) by August 4, 2003, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less then that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the NTP Executive Secretary (contact information above) by August 4, 2003, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the SACATM and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (*http://ntp-server.niehs.nih.gov*).

Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the NTP Executive Secretary and should be received by August 4, 2003, to enable review by the SACATM and NIEHS/NIH prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background

The SACATM was chartered January 9, 2002, to fulfill section 3(d) of Public Law 106–545, the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3(d)] and is composed of scientists from the public and private sectors (**Federal Register:** March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the National Institute of Environmental Health Sciences (NIEHS), the Interagency Coordinating Committee on the Validation of Alternative Toxicological Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding statutorily mandated duties of the ICCVAM and activities of the NICEATM. The committee's charter is posted on the Web at *http://iccvam.niehs.nih.gov* and is available in hard copy upon request from the NTP Executive Secretary (contact information above).

Dated: July 9, 2003.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 03–18012 Filed 7–15–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) Request for Existing Dermal and Ocular Irritancy Chemical Test Data From Animal and Human Studies Using Standardized Testing Methods

Summary

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM are collaborating with the European Centre for the Validation of Alternative Methods (ECVAM) to conduct a validation study on *in vitro* test methods for assessing dermal irritation. Future collaborative validation studies may evaluate alternative methods for assessing ocular irritancy or other hazard endpoints. On behalf of ICCVAM, the NICEATM requests the submission of existing data on commercially available chemicals tested for skin irritancy in rabbits using current standardized testing methods (*e.g.*, EPA 1998a; EPA 1998b; OECD 2001). These data will be used to help identify appropriate reference chemicals (*i.e.*, those with high-quality *in vivo* testing data) for use in the validation study. NICEATM welcomes the submission of existing data from both human and animal studies and is also interested in any human post-marketing or occupational exposure/surveillance data that might be available for these chemicals. NICEATM also requests the submission of existing, high quality ocular irritation data that might be used to identify appropriate reference chemicals for future validation studies of *in vitro* ocular irritancy test methods. Data are sought from studies conducted to comply with Federal or other national/ international testing requirements that may not be publicly available because, (1) it was submitted to regulatory authorities, but cannot be released to the public by regulatory authorities, or (2) there is no requirement to submit the data to regulatory authorities.

Request for Submission of Chemical and Protocol Information/Test Data

Data and other information submitted in response to this notice should be sent by mail, fax or e-mail to NICEATM [Dr. William S. Stokes, Director, NICEATM, NIEHS, PO Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *iccvam@niehs.nih.gov*] by noon on September 2, 2003 in order to ensure their consideration for the upcoming *in vitro* dermal irritation validation study. However, data and information received after this date will be periodically compiled and added to the database maintained by NICEATM. All chemical and protocol information/ test data submitted in response to this notice will be publicly available upon request to NICEATM.

When submitting chemical and protocol information/test data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable).

NICEATM prefers data to be submitted as copies of pages from applicable study notebooks and/or study reports, if available. Each submission for a chemical should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Chemical and/or product class
- Commercial source
- Rabbit skin/eye test protocol used
- Human skin/eye test protocol used
- Individual animal/human responses at each observation time
- The extent to which the study complied with National or International Good Laboratory Practice (GLP) guidelines
- Date and testing organization

Those persons submitting data on chemicals tested for skin and/or ocular irritancy in rabbits are referred to the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Report No. 66: Skin Irritation and Corrosion: Reference Chemicals Data Bank (March 1995) and ECETOC Technical Report No. 48: Eye Irritation: Reference Chemicals Data Bank (Second Edition, June 1998), respectively, for examples of the experimental animal study information and data that are requested in this notice. Both reports may be ordered from the ECETOC Web site at: *http://www.ecetoc.org.* Those persons submitting data on chemicals tested for skin irritation in humans are referred to Phillips, *et al.* (1972) for examples of the types of human study information and data that are requested in this notice.

The NICEATM will compile information and test data received by the deadline for consideration by ICCVAM and the ICCVAM Dermal Corrosivity and Irritancy Working Group (DCIWG). These groups will review the data and identify chemicals that might be appropriate for use in the upcoming validation study on *in vitro* test methods for dermal irritation.

Background Information on ICCVAM and NICEATM

ICCVAM was established in 1997 by NIEHS to coordinate the interagency evaluation of proposed new and alternative test methods, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. Composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information, ICCVAM promotes the scientific validation and regulatory acceptance of toxicological test methods that improve agencies' ability to make decisions on health risks, while refining, reducing, and replacing animal use wherever possible. ICCVAM was authorized as a permanent interagency committee of the NIEHS, under the NICEATM, on December 19, 2000, through passage of the ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*). Pub. L. 106–545 directs the ICCVAM to coordinate the technical review of new, revised, and alternative test methods of interagency interest. NICEATM provides operational and scientific support for ICCVAM and 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 following Web site: *http://iccvam.niehs.nih.gov.*

References

EPA. 1998a. Health Effects Test Guidelines, OPPTS 870.2500, Acute Dermal Irritation, EPA 712–C–98–196. Available: *http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870–2500.pdf.*

EPA. 1998b. Health Effects Test Guidelines, OPPTS 870.2400, Acute Eye Irritation, EPA 712–C–98–195. Available: *http://www.epa.gov/opptsfrs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/870–2400.pdf.*

OECD. 2001. Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures [ENV/JM/MONO(2001)6] Available: *http://www.oecd.org.*

Phillips L, Steinberg M, Maibach HI, Akers WA. 1972. A comparison of rabbit and human skin response to certain irritants. Toxicology and Applied Pharmacology. Mar; 21(3): 369–82.

Dated: July 9, 2003.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Announcement of and Request for Public Comments on Substances Nominated to the National Toxicology Program (NTP) for Toxicological Studies and Study Recommendations Made by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC)

Summary: The National Toxicology Program (NTP) continuously solicits and accepts nominations for toxicological studies to be undertaken by the program. Nominations of substances of potential human health concern are received from Federal agencies, the public, and other interested parties. These nominations are subject to several levels of review before selections for testing are made and toxicological studies are designed and implemented. Evaluation by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) is the initial external review step in the NTP's formal selection process for NTP study nominations. On June 10, 2003, the ICCEC met to review 14 new nominations and make study recommendations. This announcement (1) Provides brief background information regarding the substances nominated to the NTP for study, (2) presents the ICCEC's study recommendations from its June 10, 2003 meeting, (3) solicits public comment on the nominations and study recommendations, and (4) requests the submission of additional relevant information for consideration by the NTP in its continued evaluation of these nominations.

Review of Study Nominations

Evaluation by the ICCEC is the initial external step in the NTP's formal selection process for NTP study nominations. At it's meeting on June 10, 2003, the ICCEC reviewed 14 new nominations for NTP studies. For 13 of these nominations, the ICCEC recommended one or more types of toxicological studies, and for one nomination, no studies were recommended at this time. The nominated substances with CAS numbers, nomination source, nomination rationale, and specific study recommendations are given in the accompanying tables.

The ICCEC is composed of representatives from the Agency for Toxic Substances and Disease Registry,