

In Vitro Ocular Irritancy Chemical Tests: BCOP, HET-CAM, ICE, and IRE

NICEATM is especially interested in data from four *in vitro* test methods used to identify severe (irreversible) ocular irritation/corrosion: BCOP, HET-CAM, ICE, and IRE. Because test methods for identifying severe eye irritants/corrosives are of high priority, NICEATM especially requests data on chemicals identified by these four methods as severe irritants, although data on mildly irritating and non-irritating substances are also welcome.

Other In Vitro Ocular Irritancy Methods

NICEATM also requests the submission of data and information for standardized *in vitro* ocular irritancy methods, other than the four identified above, and methods that might be used to identify non-irritating and mild to moderate irritants. Detailed test method protocols and other related information for these potential test methods should be submitted along with the data.

In Vivo Test Methods for Ocular Irritancy

NICEATM requests the submission of high quality *in vivo* 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, but may not be publicly available because: (1) The data were submitted to regulatory authorities, but are proprietary and cannot be released to the public by regulatory authorities, or (2) there is no requirement to submit the data to regulatory authorities. In addition to data from studies in animals, NICEATM also welcomes the submission of data from human studies including any human post-marketing or occupational exposure/surveillance data that might be available.

Procedures for Reducing or Eliminating Pain and Suffering during In Vivo Ocular Irritancy Testing

NICEATM requests 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, such as those using topical or systemic analgesics.

Background Information

In August 2003, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) unanimously recommended that

NICEATM focus efforts on test methods for ocular irritancy and possibly hold a workshop and/or develop a background document on available methods. In October 2003, the U.S. Environmental Protection Agency nominated the following activities to ICCVAM: (1) Evaluate the validation status of the four *in vitro* ocular toxicity test methods (BCOP, IRE, ICE, and HET-CAM), (2) identify and develop *in vivo* ocular toxicity reference data to support the validation of *in vitro* test methods, (3) explore ways of alleviating pain and suffering from current *in vivo* ocular toxicity testing, and (4) review the state of the science and the availability of *in vitro* test methods for assessing mild or moderate ocular irritants. ICCVAM endorsed the review of these methods as a high priority and recommended that NICEATM develop Background Review Documents for BCOP, IRE, ICE, and HET-CAM. NICEATM convened an independent expert panel on January 11-12, 2005, to review the validation status of these four methods and develop conclusions and recommendations on standardized protocols and reference chemicals for future testing and validation studies. Availability of the expert panel's report will be announced in a future **Federal Register** notice.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from fifteen 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, and replace animal use. The ICCVAM Authorization Act of 2000 (P.L. 106-545, available at <http://iccvam.niehs.nih.gov/about/PL106545.htm>) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers and provides scientific support for the ICCVAM. 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://www.iccvam.niehs.nih.gov>.

References

EPA 1998. 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/Series/870-2400.pdf.

UN 2003. Globally Harmonized System of Classification and Labelling of Chemicals (GHS). [ST/SG/AC.10/30]. United Nations, New York and Geneva. Available: <http://www.uncece.org/trans/danger/publi/ghs/officialtext.html>.

Dated: February 17, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05-3831 Filed 2-25-05; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board to be held in March 2005.

The Drug Testing Advisory Board meeting will be open and will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and a Nuclear Regulatory Commission drug testing program update. Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to arrange special accommodations for persons with disabilities.

The Board will also meet to develop the analytical and administrative policies for the final Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program that were published as proposed revisions in the **Federal Register** on April 13, 2004 (69 FR 19673). The submissions from 285 commentators have been made available to the public on the Web site <http://workplace.samhsa.gov>. This meeting will be conducted in closed session since discussing such public comments in open session and then developing the policies will significantly frustrate the Department's ability to develop the Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS Office of General

Counsel made the determination that such matters are protected by exemption 9(B) of section 552(b)(c) of title 5 U.S.C. and therefore may be closed to the public.

To facilitate entering the building for the open session, public attendees are required to contact Mrs. Giselle Hersh, Division of Workplace Programs, 1 Choke Cherry Road, Room 2-1042, Rockville, MD 20857, 240-276-2605 (telephone), or write to Giselle.Hersh@samhsa.hhs.gov. A roster of the Board members, the transcript of the open session, and the minutes of the meeting will be available on the following Web site: <http://workplace.samhsa.gov> as soon as possible after the meeting. Additional information for this meeting may be obtained by contacting the individual listed below.

Committee Name: Substance Abuse and Mental Health Services, Administration Drug Testing Advisory Board.

Meeting Date: March 9, 2005; 8:30 a.m.–4:30 p.m.; March 10, 2005; 8:30 a.m.–4:30 p.m.

Place: SAMHSA Building, 1 Choke Cherry Road, Sugarloaf Room, Rockville, Maryland 20850.

Type: Open: March 9, 2005; 8:30 a.m.–9:30 a.m.

Closed: March 9, 2005; 9:30 a.m.–4:30 p.m.

Closed: March 10, 2005; 8:30 a.m.–4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Donna M. Bush, Ph.D., Executive Secretary 1 Choke Cherry Road, Room 2-1035, Rockville, Maryland 20857, E-mail: Donna.Bush@samhsa.hhs.gov, 240-276-2600 (telephone) or 240-276-2610 (fax).

Dated: February 22, 2005.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 05-3748 Filed 2-25-05; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1573-DR]

Indiana; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Indiana (FEMA-1573-DR), dated January 21, 2005, and related determinations.

EFFECTIVE DATE: February 16, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Indiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 21, 2005:

Jefferson County for Public Assistance. Daviess, Franklin, Gibson, Greene, Huntington, Lawrence, Martin, Pike, and Posey Counties for Public Assistance (already designated for Individual Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05-3777 Filed 2-25-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1580-DR]

Ohio; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major

disaster for the State of Ohio (FEMA-1580-DR), dated February 15, 2005, and related determinations.

DATES: *Effective Date:* February 15, 2005.

FOR FURTHER INFORMATION CONTACT:

Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 15, 2005, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Ohio, resulting from severe winter storms, flooding, and mudslides on December 22, 2004, through February 1, 2005, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Ohio.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas; and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance, Hazard Mitigation, and the Other Needs Assistance under Section 408 of the Stafford Act will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, Lee Champagne, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Ohio to have been affected adversely by this declared major disaster:

Athens, Belmont, Clark, Coshocton, Crawford, Delaware, Franklin, Henry,