DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health; Notice of Availability of Proposed Minimum Performance Standards (MPS) for Three Types of *In vitro* Methods for Assessing the Dermal Corrosivity Hazard Potential of Chemicals; Request for Comments

Summary

The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the availability of and invites public comment on proposed MPS for three types of *in Vitro* methods for assessing the dermal corrosivity hazard potential of chemicals. The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Dermal Corrosivity and Irritation Working Group (DCIWG) developed these proposed MPS. The ICCVAM developed the proposed MPS to communicate criteria which could be used to determine if similar test methods have comparable accuracy and reliability.

Availability of the Proposed MPS

Copies of the MPS are available electronically in PDF format on the ICCVAM/NICEATM web site at *http://iccvam.niehs.nih.gov* or in printed form by contacting Dr. William Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–3398, (fax) 919–541–0947, (e-mail) *iccvam@niehs.nih.gov.*

Request for Comments

NICEATM invites the submission of written comments on the proposed MPS. When submitting written comments, please refer to this **Federal Register** notice and provide applicable contact information (name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization). Written comments should be sent by mail, fax, or e-mail to NICEATM (contact information provided above) by noon on August 15, 2003. All written comments received by this date will be posted on the ICCVAM/NICEATM web site and will be considered by the DCIWG and ICCVAM during development of the final ICCVAM MPS for these assays. Final ICCVAM MPS will be published as addendums to previously published ICCVAM reports on these test methods and will be forwarded to Federal agencies for their consideration. Availability of the final MPS will be announced via a **Federal Register** notice. Copies of the MPS will be made available electronically in PDF format on the ICCVAM/NICEATM web site or can be obtained in printed form by contacting NICEATM (contact information provided above).

Supplemental Information about the Proposed MPS

ICCVAM previously evaluated and recommended four validated test methods for assessing the dermal corrosivity hazard potential of chemicals: Corrositex®, EPISKIN™, EpiDerm™ (EPI–200), and the rat skin transcutaneous electrical resistance (TER) Assay (NIEHS 1999 and NIEHS 2002). Subsequently, the U.S. Environmental Protection Agency (EPA) requested that ICCVAM establish MPS for the three proprietary dermal corrosivity test methods (Corrositex®, EPISKIN™, EpiDerm™) and the non-proprietary rat skin TER test method. In response, the ICCVAM DCIWG drafted proposed MPS based on the validated reference test methods for these three types of *in vitro* dermal corrosivity assays: membrane barrier test methods, human skin model system test methods, and skin TER test methods.

The purpose of the MPS is to communicate the basis on which a validated and accepted proprietary (*e.g.*, copyrighted, trademarked, registered) or non-proprietary test method has been determined to have sufficient accuracy and reliability for a specific testing purpose. Accuracy refers to the ability of the test method to correctly predict or measure the biological effect of interest (also referred to as relevance) while reliability refers to the extent of intra- and inter-laboratory reproducibility. MPS also provide the criteria that should be met by other proposed test methods that are based on similar scientific principles and that measure or predict the same biological or toxic effect.

The three elements of MPS are:

- Minimum procedural standards that identify essential structural, functional, and procedural components of the validated reference test method (*e.g.*, procedural details, proper controls, morphologic structure and integrity of the test system, biological identity of key components, and expected biological responsiveness). Adherence to the minimum procedural standards will help to assure that the proposed test method is based on the same concepts as the referenced test method.
- A list of recommended reference chemicals that can be used to assess the accuracy and reliability characteristics of the proposed test method. The list includes substances that are representative of the chemical and product classes for which the validated test method is considered applicable, as well as substances that are representative of the range of responses (*e.g.*, negative, weak to strong positive) that the validated test method is capable of measuring or predicting.
- The accuracy and reliability that should be achieved by the proposed test method when evaluated using the minimum list of reference chemicals.

Background Information on ICCVAM and NICEATM

The NIEHS established the ICCVAM in 1997 to coordinate the interagency technical review of new, revised, and alternative test methods of interagency interest, and to coordinate cross-agency issues relating to the validation, acceptance, and national/international harmonization of toxicological testing methods. ICCVAM was established as a permanent interagency committee of the NIEHS under the NICEATM on December 19, 2000, by the ICCVAM Authorization Act of 2000 (Pub. L. 106–545, available at *http://iccvam.niehs.nih.gov/about/PL106545.pdf.* The Committee is composed of representatives from fifteen Federal regulatory and research agencies that use or generate toxicological information. Its purpose is to promote the scientific validation and regulatory acceptance of toxicological test methods that will improve the agencies' ability to accurately assess the safety or hazards of chemicals and various types of products, while refining, reducing, and replacing animal use wherever possible. 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

NIEHS. 1999. Corrositex® An *In Vitro* Test Method for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 99–4495. Available at: *http://iccvam.niehs.nih.gov/methods/corrode.htm.*

NIEHS. 2002. ICCVAM Evaluation of EPISKIN™, EpiDerm™ (EPI–200), and the Rat Skin Transcutaneous Electrical

Resistance (TER) Assay: *In Vitro* Test Methods for Assessing Dermal Corrosivity Potential of Chemicals. NIH Publication No. 02–4502. Available at *http://iccvam.niehs.nih.gov/methods/epiderm.htm.*

Dated: June 12, 2003.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301–443–6014 (voice), 301–443–3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification, a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines, the following laboratories meet the minimum standards set forth in the Mandatory Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016, (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–6870, (Formerly: Jewish Hospital of Cincinnati, Inc.).

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917.

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093, (Formerly: Cox Medical Centers).

Diagnostic Services Inc., dba DSI, 12700 Westlinks Dr., Fort Myers, FL 33913, 239–561–8200/800–735–5416.

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912–244–4468.

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2661/800–898–0180, (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310.

Dynacare Kasper Medical Laboratories*, 10150–102 St., Suite 200, Edmonton, Alberta, Canada TJ5 5E2, 780–451–3702/800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609.

Express Analytical Labs, 3405 7th Ave., Suite 106, Marion, IA 52302, 319–377–0500.

Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519–679–1630.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Laboratory Specialists, Inc.).

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Rd., Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Dr., Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 10788 Roselle St., San Diego, CA 92121, 800–882–7272, (Formerly: Poisonlab, Inc.).

Laboratory Corporation of America Holdings, 1120 Stateline Rd. West, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).