ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials,'' dated April 2005. The draft guidance provides sponsors of vaccine trials with recommendations on assessing the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials. In particular, the draft guidance includes toxicity grading scale tables to use as a guideline for selecting the assessment criteria.

DATES: Submit written or electronic comments on the draft guidance by August 1, 2005 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials'' dated April 2005. The draft guidance provides sponsors of vaccine trials with toxicity grading scale tables as a guideline for selecting the criteria to assess the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials. The parameters in the tables are not necessarily warranted for every clinical trial of healthy volunteers. The parameters monitored should be appropriate for the specific study vaccine. In addition, the use of toxicity grading scales to categorize adverse events observed during clinical trials does not replace regulatory requirements to monitor, investigate, and report adverse events.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8634 Filed 4–29–05; 8:45 am]

BILLING CODE 4160–01–S

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). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

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 the 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, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (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 Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens 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 undergo 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 described 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 dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

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.

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.

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

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

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 T5J 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.

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 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734.

MAXXAM Analytics Inc.,* 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700. (Formerly: NOVAMANN (Ontario) Inc.).

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651–636–7466/800–832–3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Dr., Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515.

Northwest Toxicology, a LabOne Company, 2282 South Presidents Drive, Suite C, West Valley City, UT 84120, 801–293–2300/800–322–3361. (Formerly: LabOne, Inc., d/b/a Northwest Toxicology; NWT Drug Testing, NorthWest Toxicology, Inc.; Northwest Drug Testing, a division of NWT Inc.).

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774. (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134.

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942. (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7897 x7.

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372/800–821–3627.

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590/800–729–6432. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800–824–6152. (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866/800–433–2750. (Formerly: Associated Pathologists Laboratories, Inc.).

Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610–631–4600/877–642–2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995/847–885–2010. (Formerly: SmithKline Beecham Clinical Laboratories; International Toxicology Laboratories).

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405,

818–989–2520/800–877–2520. (Formerly: SmithKline Beecham Clinical Laboratories).
Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130.
Sciteck Clinical Laboratories, Inc., 317 Rutledge Rd., Fletcher, NC 28732, 828–650–0409.
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x276.
Southwest Laboratories, 4645 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.
Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–364–7400. (Formerly: St. Lawrence Hospital & Healthcare System).
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.
Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166, 305–593–2260.
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS certified laboratories and participate in the NLCP certification maintenance program.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 05–8746 Filed 4–29–05; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2005–0033]

Notice of Meeting of Homeland Security Science and Technology Advisory Committee

AGENCY: Office of Studies and Analysis, Science and Technology Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Homeland Security Science and Technology Advisory Committee (HSSTAC) will meet in closed session.

DATES: May 18, 2005 and May 19, 2005.

ADDRESSES: If you wish to submit comments, you must do so by May 10, 2005. Comments must be identified by DHS–2005–0033 and may be submitted by one of the following methods:

- *EPA Federal Partner EDOCKET Web site:* http://www.epa.gov/feddocket. Follow instructions for submitting comments on the Web site.
- *E-mail:* HSSTAC@dhs.gov. Include docket number in the subject line of the message.
- *Fax:* 202–254–6177.
- *Mail:* Ms. Brenda Leckey, Office of Studies and Analysis, Science and Technology Directorate, Department of Homeland Security, Washington, DC 20528.

Docket: For access to the docket to read background documents or comments received, go to *http://www.epa.gov/feddocket.*

FOR FURTHER INFORMATION CONTACT: Brenda Leckey, Office of Studies and Analysis, Science and Technology Directorate, Department of Homeland Security, Washington, DC 20528, *HSSTAC@dhs.gov,* 202–254–5041.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App. 1 *et seq.*). The HSSTAC will meet for purposes of: (1) Observing, reviewing, and evaluating operational sites where Science and Technology products are apparent and where the systems engineering challenges are visible; (2) receiving a report from the Under Secretary for Science and Technology on how the prior year HSSTAC recommendations are being/will be implemented; (3) receiving a briefing on the Maritime Domain Awareness (MDA) Architecture; (4) touring, observing and evaluating DHS operational sites and facilities; and (5) receiving subcommittee reports.

Specifically, the HSSTAC will receive briefings and tours that will include information and demonstrations detailing law enforcement methods and techniques utilized to prevent terrorists from entering our nation and carrying out catastrophic events on our air transportation system. They will observe demonstrations of two databases used to identify potential repeat criminal offenders, non-intrusive inspection equipment, evolving ''older technology'' (non-integrated, handheld, etc.), and canine operations. The HSSTAC will review the results of its subcommittees' activities undertaken since the last quarterly meeting in February 2005, and discuss any proposed subcommittee recommendations. They will receive a report from the Under Secretary detailing proposed actions and actions being taken by the Directorate as a result of the recommendations contained in the HSSTAC annual report to the Under Secretary and Congress. Finally, they will receive a classified briefing on MDA, a ''global'' program that attempts to assess any potential threat posed by vessels, cargo, and people involved in the Maritime Environment, and will tour the Joint Harbor Operations Center.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. 1 *et seq.*) and pursuant to the authority delegated to him by the Secretary in DHS Management Directive 2300, the Under Secretary for Science and Technology has determined that this HSSTAC meeting will address: Classified matters of national security concern; internal administrative and personnel matters specific to committee and agency operations; matters pertaining to law enforcement activity; and matters the disclosure of which would be likely to frustrate significantly proposed agency actions. Accordingly, consistent with the provisions of 5 U.S.C. 552b(c)(1), (c)(2), (c)(7), and (c)(9)(B), the meeting will be closed to the public.