

Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4212, Silver Spring, MD 20993-0002, 301-796-2270; or

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Stephen Ripley, Center for Biologics Evaluation and Research, 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FDA is announcing the availability of a draft guidance for industry entitled "Non-Inferiority Clinical Trials." The draft guidance includes four parts. The first part is a discussion of regulatory, study design, scientific, and statistical issues associated with the use of non-inferiority studies when these are used to establish the effectiveness of a new drug or therapeutic biologic product. The second part focuses on some of these issues in more detail, notably the quantitative analytical and statistical approaches used to determine the non-inferiority margin for use in NI studies, as well as the advantages and disadvantages of available methods. The third part addresses commonly asked questions about NI studies and provides practical advice about various approaches. The fourth part includes five examples of successful and unsuccessful efforts to define non-inferiority margins and conduct NI studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on non-inferiority clinical trials. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see

ADDRESSES) written or electronic comments regarding this document. 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 brackets in the heading of this document. Received comments may be seen 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 document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: February 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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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). 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://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One 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, 345 Hill Ave., Nashville, TN 37210, 615-255-2400. (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, 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 Road, Lenexa, KS 66215-2802, 800-445-6917.
- Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229-671-2281.
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310.
- DynaLIFE Dx, * 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876. (Formerly: Dynacare Kasper Medical Laboratories)
- ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.
- Gamma-Dynacare Medical Laboratories, * A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630.
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823. (Formerly: Laboratory Specialists, Inc.)
- Kroll Laboratory Specialists, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130. (Formerly: Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)
- Laboratory Corporation of America Holdings, 7207 N. Gessner Road, 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 Drive, 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, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339. (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center.)
- LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
- Maxxam Analytics, * 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700. (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.)
- MedTox Laboratories, Inc., 402 W. County Road 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 Drive, Minneapolis, MN 55417, 612-725-2088.
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.
- 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)
- 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, 509-755-8991/800-541-7891x7.
- Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555.
- 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, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
- Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 866-370-6699/818-989-2521. (Formerly: SmithKline Beecham Clinical Laboratories)
- 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 x1276.
- Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602-438-8507/800-279-0027.
- St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052.
- STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800-442-0438.
- 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.

Dated: February 22, 2010.

Elaine Parry,

Director, Office of Program Services, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as