

SUPPLEMENTARY INFORMATION:**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of December 17, 2007 (72 FR 71416), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter." The notice gave interested persons an opportunity to submit comments by February 15, 2008.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the

ICH Regions; Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter" was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2008.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Test for Particulate Contamination: Subvisible Particles General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: December 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-214 Filed 1-8-09; 8:45 am]

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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 Sciences Corporation, 345 Hill Ave., Nashville, TN 37210, 615-255-2400, (Formerly: 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.

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

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, 509-755-8991/800-541-7891 x7.

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 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 N.W. 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 following laboratory will be voluntarily withdrawing from the NLCP on January 9, 2009:

Oregon Medical Laboratories, 123 International Way, Springfield, OR 97477, 541-341-8092.

*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.

Elaine Parry,

Acting Director, Office of Program Services, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2462-08; DHS Docket No. USCIS-2008-0076]

RIN 1615-ZA80

Change in Filing Location for EB-5-Related Petitions and Applications and Regional Center Proposals

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Notice.

SUMMARY: This Notice announces the requirement that petitions and

applications related to the Alien Entrepreneur (EB-5) immigrant classification, and Regional Center Proposals under the EB-5 Immigrant Investor Pilot Program, must be filed at the California Service Center (CSC). Currently, EB-5-related petitions and applications are filed at either the Texas Service Center (TSC) or the CSC, depending on where the alien's commercial enterprise is located. Regional center proposals are being submitted to the Chief of USCIS Service Centers at USCIS Headquarters. The change to one filing location for EB-5-related petitions, applications, and regional center proposals announced by this Notice is necessary to improve the efficiency in the processing of EB-5-related filings.

DATES: This Notice is effective January 26, 2009 for the filing of Forms I-526, I-829, and Forms I-485 based on an approved Form I-526. This Notice is effective January 26, 2009 for the filing of Regional Center Proposals under the Immigrant Investor Pilot Program.

FOR FURTHER INFORMATION CONTACT: Joseph P. Whalen, Adjudications Officer, Service Center Operations, EB-5 Investor Program, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue, NW., Washington, DC 20529-2060, telephone (202) 272-8355.

SUPPLEMENTARY INFORMATION:

I. Background

A. EB-5 Immigrant Classification

The employment creation immigrant classification (referred to as the "Employment Based (EB-5)" immigrant classification) allows qualifying aliens, and any accompanying spouses and children, to obtain lawful permanent resident (LPR) status if the qualifying aliens have invested, or are actively in the process of investing, \$1 million in a new commercial enterprise. *See* Immigration and Nationality Act (INA) secs. 203(b)(5)(A) and (C), 8 U.S.C. 1153(b)(5)(A) and (C). Their investment must benefit the U.S. economy and create full-time jobs for 10 or more qualifying employees. INA sec. 203(b)(5)(A)(ii), 8 U.S.C. 1153(B)(5)(A)(ii). If the investment is in a rural area or an area that has experienced high unemployment (referred to as "Targeted Employment Area"), the required capital investment amount is \$500,000 rather than \$1 million. INA sec. 203(b)(5)(C)(ii), 8 U.S.C. 1153(b)(5)(C)(ii); 8 CFR 204.6(f)(2). Also, under the Immigrant Investor Pilot Program, qualifying aliens may meet the job creation requirement through the creation of 10 indirect jobs.

See Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993, sec. 610(c), Public Law 102-395, 106 Stat. 1874 (1992), 8 U.S.C. 1153 note. To qualify for the relaxed job creation requirement, an alien must invest in a new commercial enterprise that is located in a geographical region of the United States covered by a "regional center" (defined in 8 CFR 204.6(e)) approved by USCIS for participation in the pilot program. This pilot program is set to expire on March 6, 2009. *See* Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, Div. A, sec. 144, Public Law 110-329, 122 Stat. 3574, 3581 (2008). USCIS approves a regional center based on the submission of a proposal which successfully:

- Describes how the regional center will promote economic growth in a particular geographical region of the United States;
- Describes how jobs will be indirectly created;
- Specifies the amount and source of capital committed to the regional center;
- Describes the manner in which the regional center will have a positive impact on the economy; and is
- Supported by economically or statistically valid forecasting tools. 8 CFR 204.6(m)(3).

Obtaining LPR status under the EB-5 immigrant classification is a three step process, as follows:

(1) The alien must first be classified as an alien entrepreneur. This step requires the alien to obtain an approval of a Form I-526, "Immigrant Petition by Alien Entrepreneur." *See* 8 CFR 204.6(a).

(2) The alien then applies to become a conditional resident on the basis of the approved Form I-526 petition. If the alien resides in the United States, he or she must obtain a grant of a Form I-485, "Application to Register Permanent Residence or Adjust Status" from USCIS to become a conditional resident. *See* 8 CFR 245.1(a). If the alien resides outside of the United States, he or she must obtain an immigrant visa issued by the Department of State (DOS) and gain admission to the United States on this basis. Foreign Affairs Manual 9 FAM 42.32(e) N12. After completing one of these steps, the alien will obtain conditional resident status. INA section 216A(f)(1), 8 U.S.C. 1186b(f)(1).

(3) The last step to obtaining LPR status is triggered 90 days before the second anniversary of the alien entrepreneur's conditional resident status. INA section 216A(d)(2), 8 U.S.C. 1186b(d)(2). During this 90-day period, the alien entrepreneur must submit to