

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Compliance Program 7348.808: Bioresearch Monitoring; Good Laboratory Practices (GLP) (Nonclinical)	August 8, 1994	FDA Staff Personnel	Do
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A: EPA Data Audit Inspections	October 1, 1991	Do	Do
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	August 18, 1994	Do	Do
Compliance Program 7348.809: Bioresearch Monitoring; Institutional Review Board	August 18, 1994	Do	Do
Compliance Program 7348.811: Bioresearch Monitoring; Clinical Investigations	August 18, 1994	Do	Do

VIII. International Conference on Harmonization Guidances (CDER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
E2B Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Regulated Industry	Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573 or 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, 1-800-835-4709 or 301-827-1800, FAX Information System: 1-888-CBER-FAX (within the United States) or 301-827-3844 (outside of the United States and local to Rockville, MD). Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm
E8 General Considerations for Clinical Trials	December 17, 1997	Do	Do
M3 Timing of Nonclinical Studies for the Conduct of Human Clinical Trials of Pharmaceuticals	November 25, 1997	Do	Do
QC3 Impurities; Residual Solvents	December 24, 1997	Do	Do
S1B Testing for Carcinogenicity of Pharmaceuticals	February 23, 1998	Do	Do
S1C(R) Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do

Dated: June 25, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-17702 Filed 7-2-98; 8:45 am]

BILLING CODE 4160-01-F

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, and Laboratories That Have Withdrawn From the Program

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted

from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: <http://www.health.org>

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

Special Note: Our office moved to a different building on May 18, 1998. The above address is now the correct one to use for all regular mail and correspondence. For all overnight mail service use the following: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which 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 Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

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

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840 (formerly: Bayshore Clinical Laboratory)
Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400
Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931/334-263-5745

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513-569-2051 (formerly: Jewish Hospital of Cincinnati, Inc.)
American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703-802-6900
Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750
Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801-583-2787/800-242-2787
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)
Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305-325-5784
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)
Dept. of the Navy, Navy Drug Screening Laboratory, P. O. Box 88-6819, Great Lakes, IL 60088-6819, 847-688-2045/847-688-4171
Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941-418-1700/800-735-5416
Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912-244-4468
DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800-898-0180/206-386-2672 (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,* 14940-123 Ave., Edmonton, Alberta, Canada T5V 1B4, 800-661-9876/403-451-3702
ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601-236-2609
Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ON, Canada N6A 1P4, 519-679-1630
General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267

Hartford Hospital Toxicology Laboratory, 80 Seymour St., Hartford, CT 06102-5037, 860-545-6023
LabCorp Occupational Testing Services, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-672-6900/800-833-3984 (formerly: CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)
LabCorp Occupational Testing Services, Inc., 4022 Willow Lake Blvd., Memphis, TN 38118, 901-795-1515/800-223-6339 (formerly: MedExpress/National Laboratory Center)
LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913-888-3927/800-728-4064 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)
Laboratory Corporation of America, 888 Willow St., Reno, NV 89502, 702-334-3400 (formerly: Sierra Nevada Laboratories, Inc.)
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800-437-4986/908-526-2400 (formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823
Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734/800-331-3734
MAXXAM Analytics Inc.,* 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905-890-2555 (formerly: NOVAMANN (Ontario) Inc.)
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43614, 419-381-5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302-655-5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800-832-3244/612-636-7466
Methodist Hospital Toxicology Services of Clarian Health Partners, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317-929-3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800-752-1835/309-671-5199
MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-4512/800-950-5295

- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612-725-2088
- National Toxicology Laboratories, Inc., 1100 California Ave. Bakersfield, CA 93304, 805-322-4250
- Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800-322-3361/801-268-2431
- Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440-0972, 541-341-8092
- Pacific Toxicology Laboratories, 1519 Pontius Ave., Los Angeles, CA 90025, 310-312-0056 (formerly: Centinela Hospital Airport Toxicology Laboratory).
- Pathology Associates Medical Laboratories, 11604 E. Indiana, Spokane, WA 99206, 509-926-2400/800-541-7891
- PharmChem Laboratories, Inc., 1505-A O'Brien Dr., Menlo Park, CA 94025, 650-328-6200/800-446-5177
- PharmChem Laboratories, Inc., Texas Division, 7610 Pebble Dr., Fort Worth, TX 76118, 817-595-0294 (formerly: Harris Medical Laboratory)
- Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913-339-0372/800-821-3627
- Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 619-279-2600/800-882-7272
- Premier Analytical Laboratories, 15201 East I-10 Freeway, Suite 125, Channelview, TX 77530, 713-457-3784/800-888-4063 (formerly: Drug Labs of Texas)
- Presbyterian Laboratory Services, 5040 Airport Center Parkway, Charlotte, NC 28208, 800-473-6640/704-943-3437
- Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 810-373-9120/800-444-0106 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)
- Quest Diagnostics Incorporated, National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410-536-1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science, CORNING National Center for Forensic Science)
- Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800-526-0947/972-916-3376 (formerly: Damon Clinical Laboratories, Damon/MetPath, CORNING Clinical Laboratories)
- Quest Diagnostics Incorporated, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220-3610, 800-574-2474/412-920-7733 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories, CORNING Clinical Laboratories)
- Quest Diagnostics Incorporated, 2320 Schuetz Rd., St. Louis, MO 63146, 800-288-7293/314-991-1311 (formerly: Metropolitan Reference Laboratories, Inc., CORNING Clinical Laboratories, South Central Division)
- Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108-4406, 800-446-4728/619-686-3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute, CORNING Clinical Laboratories)
- Quest Diagnostics Incorporated, One Malcolm Ave., Teterboro, NJ 07608, 201-393-5590 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratory)
- Quest Diagnostics Incorporated, 1355 Mittel Blvd., Wood Dale, IL 60191, 630-595-3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories, CORNING Clinical Laboratories Inc.)
- Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804-378-9130
- Scott & White Drug Testing Laboratory, 600 S. 31st St., Temple, TX 76504, 800-749-3788/254-771-8379
- S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505-727-8800/800-999-LABS
- SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590 (formerly: SmithKline Bio-Science Laboratories)
- SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214-637-7236 (formerly: SmithKline Bio-Science Laboratories)
- SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352-787-9006 (formerly: Doctors & Physicians Laboratory)
- SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800-877-7484/610-631-4600 (formerly: SmithKline Bio-Science Laboratories)
- SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847-447-4379/800-447-4379 (formerly: International Toxicology Laboratories)
- SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91405, 818-989-2520 / 800-877-2520
- South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219-234-4176
- Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602-438-8507
- Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517-377-0520 (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, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573-882-1273
- Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260
- UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800-492-0800/818-996-7300 (formerly: MetWest-BPL Toxicology Laboratory)
- Universal Toxicology Laboratories, LLC, 10210 W. Highway 80, Midland, Texas 79706, 915-561-8851/888-953-8851
- UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555-0551, 409-772-3197

The following laboratory is voluntarily withdrawing from the National Laboratory Certification Program on July 31, 1998: TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818-226-4373/800-966-2211 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)

*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. DHHS, with the DHHS' National Laboratory Certification Program (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, the DHHS will recommend that DOT certify the laboratory (**Federal Register**, 16 July 1996) as meeting the minimum standards of the "Mandatory Guidelines for Workplace Drug Testing" (59 Federal Register, 9 June 1994). After receiving the DOT certification, the laboratory will be included in the monthly list of DHHS certified laboratories and participate in the NLCP certification maintenance program.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98-17846 Filed 7-2-98; 8:45 am]

BILLING CODE 4160-20-P

DEPARTMENT OF THE INTERIOR

National Recreation Lakes Study

AGENCY: National Recreation Lakes Study.

ACTION: Notice of First Commission Meeting, National Recreation Lakes Study.

SUMMARY: The Omnibus Parks and Public Land Management Act of 1996 authorizes a presidential commission to review the demand for recreation at Federal lakes, and to develop alternatives for enhanced recreation uses, primarily through innovative public/private partnerships. This will be the first meeting of the Commissioner-designees and Staff.

DATES: July 20-21, 1998, starting at 8 a.m.

ADDRESSES: The briefing will be held at the National Association Public Administration Conference Room, First Floor, 800 North Capitol Street, NW, Washington, D.C. 20001. Please have photo identification available for admission into the building. The agenda will consist of the following: Swearing-In Ceremony for Appointed Commissioners; Election of a Vice Chairman; Overview of the Status of Recreation at Federal Lakes; Discussion of Proposed Goals; Study Process/Action Plan; Presentation of Findings Reports; Subgroups & Topic Experts; Communications Plan; Study Duration & Report Due Date; Public Comment Period; Necessary Decisions on Above Agenda Topics; Future Meetings; Time and Place of Next Meeting; and the Adjournment.

FOR FURTHER INFORMATION CONTACT: Jeanne Whittington, 202-219-7104.

Dated: June 30, 1998.

Jana Prewitt,

Executive Director, National Recreation Lakes Study.

[FR Doc. 98-17961 Filed 7-2-98; 8:45 am]

BILLING CODE 4310-94-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Draft Environmental Assessment and Land Protection Plan for the Proposed Establishment of Swayze Lake National Wildlife Refuge, St. Landry Parish, LA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of the Draft Environmental Assessment and Land Protection Plan for the Proposed Establishment of Swayze Lake National Wildlife Refuge.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service, Southeast Region, proposes to establish a new national wildlife refuge in the Swayze Lake area in St. Landry Parish, Louisiana. The purpose of the proposed refuge is to protect, enhance, and manage a diversity of fish and wildlife habitats in the Swayze Lake area for the benefit of the area's fishery, resident and migratory waterfowl, shorebirds, wading birds, neotropical migratory birds, the federally listed Louisiana black bear, and other native wildlife. A Draft Environmental Assessment and Land Protection Plan for the establishment of the proposed refuge has been developed by Service biologists in coordination with the Louisiana Department of Wildlife and Fisheries, the Natural Resources Conservation Service, parish officials, and other local entities. The assessment considers the biological, environmental, and socioeconomic effects of establishing the proposed refuge and evaluates three alternative actions and their potential impacts on the environment. Written comments or recommendations concerning the proposal are welcomed and should be sent to the address given below.

DATES: Land acquisition planning for the project is currently underway. The draft environmental assessment and land protection plan will be available to the public for review and comment on July 15, 1998. Written comments must be received no later than August 14, 1998, in order to be considered for the preparation of the final environmental assessment.

ADDRESSES: Comments and requests for copies of the draft environmental assessment and for further information on the project should be addressed to Mr. Charles R. Danner, Team Leader, Planning and Support Team, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, Georgia 30345, or by telephone at 800/419-9582.

SUPPLEMENTARY INFORMATION: The proposed refuge area consists primarily of bottomland hardwoods, wooded/shrub swamps, and other wetlands. It covers a total of approximately 20,000 acres and is located within the Atchafalaya River Basin, about 5 miles northwest of Krotz Springs in St. Landry Parish, Louisiana. The Service proposes to establish the refuge by purchasing about 9,000 acres in fee title from willing sellers. The remaining 11,000 acres would be sought through conservation easements, cooperative agreements, or fee title purchases, depending on landowner willingness.

The Swayze Lake area is nationally significant because it provides wintering habitat for migratory waterfowl, breeding habitat for wood ducks, migration habitat for shorebirds and neotropical migratory birds, and year-round habitat for wading birds. It is also a feeding area for bald eagles. The bottomland hardwoods also provide important habitat for the federally listed Louisiana black bear. Other resident wildlife include the American alligator, white-tailed deer, swamp rabbit, and furbearers such as raccoon, mink, muskrat, and otter.

The area's freshwater fishery is excellent. Numerous bayous and backwater lakes are interspersed throughout the area and provide outstanding sportfishing opportunities. Freshwater game species are abundant and include largemouth bass, black and white crappie, bluegill, and several species of catfish. Crawfishing is also extremely popular.

Dated: June 22, 1998.

Sam D. Hamilton,

Regional Director.

[FR Doc. 98-17724 Filed 7-2-98; 8:45 am]

BILLING CODE 4310-55-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK-962-1410-00-P]

Notice for Publication; Alaska Native Claims Selection

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that decisions to issue conveyance under the provisions of Sec. 14(h)(8) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(h)(8), will be issued to the Bering Straits Native Corporation for approximately 14,169 acres. The lands involved are in the vicinity of Iron Creek, Alaska, and are within T. 6 S., R. 30 W., Kateel River Meridian, Alaska.