review those applications in 60 days and approved Accredited Persons may begin to submit reviews of 510(k)'s on November 21, 1998. Because Accredited Persons must participate in training prior to submitting recommendations, applicants who wish to attend the initial training that will be held October 14 through 16, 1998, should submit their applications at least 60 days in advance of that date.

II. Significance of Guidance

This guidance represents the agency's current thinking on implementation of the third party review program. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance has been issued under the agency's procedures for a Level 1 guidance document.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so using the WWW. CDRH maintains an entry on the WWW for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997,'' device safety alerts, access to **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers addresses), small manufacturers assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

A text-only version of the CDRH home page is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, at any time, submit written comments regarding this final guidance to the contact person listed above. Comments will be considered when determining whether to amend the current guidance.

Dated: October 26, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29275 Filed 10–30–98; 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. Please use the above address for all regular mail and correspondence. For all overnight mail service use the following address: 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, 513–585–9000, (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, Great Lakes, IL, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 941–561–8200/800–735–5416

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

Info-Meth, 112 Crescent Ave., Peoria, IL 61636, 800–752–1835/309–671–5199, (formerly: Methodist Medical Center Toxicology Laboratory)

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

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

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, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/ 800–999–5227

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 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 (FR, 16 July 1996) as meeting the minimum standards of the ''Mandatory Guidelines for Workplace Drug Testing'' (59 FR, 9 June 1994, Pages 29908–29931). 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. 98–29246 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Substance Abuse and Mental Health Services Administration

Notice of Listing of Members of the Substance Abuse and Mental Health Services Administration's Senior Executive Service Performance Review Board (PRB)

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the persons who will serve on the Substance Abuse and Mental Health Services Administration's Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the SAMHSA Performance Review Board, which oversees the evaluation of performance appraisals of SAMHSA's Senior Executive Service (SES) members: Joseph Autry, M.D., Chairperson; Bernard S. Arons, M.D.; Ruth Sanchez-Way, Ph.D.; and William Robinson, M.D.

For further information about the SAMHSA Performance Review Board, contact the Division of Human Resources Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 14 C–24, Rockville, Maryland 20857, telephone (301) 443–5030 (not a toll-free number).

Dated: October 26, 1998.

Nelba Chavez,

Administrator, SAMHSA.

[FR Doc. 98–29266 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–6333–00; GP9–0016]

Closure of Public Lands; Oregon

AGENCY: Bureau of Land Management, Medford District Office, Ashland Resource Area.

ACTION: Emergency Closure of Bureau of Land Management Administered Roads—Jackson County, Oregon.

SUMMARY: Notice is hereby given that certain BLM roads in Jackson County, Oregon are hereby closed to all motorized vehicles including off-road vehicles from October 23, 1998 until notice is rescinded. The closure is made under the authority of 43 CFR 9268.3(d)(1)(ii) and 8364.1(a).

The roads and the conditions of this emergency road closure are identified as follows: Roads 41–2E–3, 41–2E–9, 41–2E–10.0, 41–2E–10.1 and connecting spur roads are hereby seasonally closed. These roads are located in Sections 2, 3, 10, 11, and 12 of T. 41 S., R. 2 E., and Sections 5, 6, and 7 of T.41S., R. 3E., Willamette Meridian, Jackson County, Oregon. In addition, the road located next to Scotch Creek in Section 1, T. 41 S., R. 2 E. (W. M.) is hereby permanently closed under this order.

Any person who fails to comply with the provisions of this closure order may be subject to the penalties provided in 43 CFR 8360.0–7, which include a fine not to exceed $1,000.00 and/or imprisonment not to exceed 12 months, as well as the penalties provided under Oregon State law.

The roads temporarily closed to motorized use under this order will be posted with signs at barricaded locations.

The purpose of this emergency temporary closure is to prevent excessive erosion, and to protect recent BLM investments in road maintenance work.

This closure is effective from October 23, 1998 until this notice is rescinded.

FOR FURTHER INFORMATION CONTACT: Joe Hoppe, Realty Specialist, at (541) 770–2200.

Dated: October 23, 1998.

Wayne M. Kuhn,

Acting District Manager.

[FR Doc. 98–29270 Filed 10–30–98; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF INTERIOR

Bureau of Land Management

[UT–069–1990–00]

San Juan and Grand Resource Management Plans; Notice of Intent

AGENCY: Bureau of Land Management, Interior.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent to prepare Environmental Impact Statement (EIS) and amend the San Juan Resource Management Plan (SJRMP)and the Grand Resource Management Plan (GRMP). Call for information on potential Areas of Critical Environmental Concern (ACEC) and Wild and Scenic Rivers (W&SR).