1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

The draft document is intended to serve as an adjunct to FDA's ''Points to Consider (PTC) in Safety Evaluation of Hemoglobin-Based Oxygen Carriers,'' which is dated August 27, 1990. That PTC was announced as available in the **Federal Register** of January 8, 1991 (56 FR 698), and was published in the April 1991 issue of *Transfusion* (31: 369–371, 1991). This draft document was developed, in part, from presentations and discussions at the ''Workshop on Criteria for Efficacy of Red Cell Substitutes,'' held in Bethesda, MD, on January 11, 1994, and sponsored by the National Heart, Lung, and Blood Institute, the Department of the Army, and FDA. The draft document is intended as general guidance for manufacturers, investigators, sponsors, and other parties interested in the design, endpoints, and efficacy criteria for clinical trials of hemoglobin- and perfluorocarbon-based oxygen carrier products.

This guidance document represents the agency's current thinking on hemoglobin- and perfluorocarbon-based oxygen carriers. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. This document is intended to provide information and does not set forth requirements. FDA encourages manufacturers, sponsors, investigators, and other interested parties to prospectively discuss with FDA the design of clinical trials, selection of clinical trial endpoints, and development of efficacy criteria to prevent expenditure of time, personnel, money, and other resources on clinical trials that FDA may later determine are unacceptable.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by December 8, 1997,, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of this document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23655 Filed 9–5–97; 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 (Formerly: National Institute on Drug Abuse, ADAMHA, 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, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

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 Laboratory, 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

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 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
Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020
Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917
CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)
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, 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
ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609
General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267
Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300 (formerly: Harrison & Associates Forensic Laboratories)
Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051
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
MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38118, 901–795–1515/800–526–6339
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, 235 N. Graham St., Portland, OR 97227, 503–413–4512, 800–237–7808(x4512)
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
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, 415–328–6200/800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 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, 1851 East Third Street, Charlotte, NC 28204, 800–473–6640
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. 25th 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
St. Anthony Hospital Toxicology Laboratory, PO Box 205, 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
TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373 / 800–966–2215 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)
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) Laboratory Accreditation Program for Substances of Abuse (LAPSA) has been given deemed status by the Department of Transportation. The SCC has accredited the following Canadian laboratory for the conduct of forensic urine drug testing required by Department of Transportation regulations:

MAXXAM Analytics Inc., 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905–890–2555 (formerly: NOVAMANN (Ontario) Inc.)

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 97–23736 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of Draft Environmental Impact Statement for the Establishment of the Northern Tallgrass Prairie Habitat Preservation Area in Western Minnesota and Northwestern Iowa

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) has prepared a Draft Environmental Impact Statement (DEIS) which is available for public review. The DEIS evaluates the establishment of a Northern Tallgrass Prairie Habitat Preservation Area as a means of working with individuals, groups, and governmental entities to permanently preserve remnant tracts of northern tallgrass prairie. Three alternatives, including a No Action alternative are being considered. The action alternatives are aimed at permanently protecting and enhancing prairie remnants.

The Service's preferred alternative (Alternative B) is to permanently protect and enhance prairie remnants through partnerships, incentives, education, and cooperative agreements. Any conservation easements, or acquisition of full title would be done by the Service and Service Partners. Service acquisition of easements and fee interest in lands would be on a voluntary basis from willing sellers.

DATES: Public comment on the DEIS is solicited pursuant to National Environmental Policy Act regulations (40 CFR 1503.1). All agencies and individuals are urged to provide comments and suggestions for improving the DEIS. The formal comment period extends for a 60-day period from the date of distribution of the DEIS. All comments received by November 6, 1997, will be considered in preparation of the Final EIS. Formal comments will be received at any time during this 60-day period in person, by mail, or at the open house (specific locations and times are listed under **SUPPLEMENTARY INFORMATION**).

WRITTEN COMMENTS SHOULD BE ADDRESSED TO: Jane West, Project Manager, U.S. Fish and Wildlife Service, BHW Federal Building, 1 Federal Drive, Fort Snelling, MN 551121–4056.

FOR FURTHER INFORMATION CONTACT: Jane West at the address listed above or by telephone at 612/725–3306.

SUPPLEMENTARY INFORMATION: America's native grasslands are a vanishing ecosystem, and mounting evidence indicates that many species are disappearing as fast as the prairie habitats on which they depend. Few other ecosystem types have experienced as great a degree of loss and alteration. In Minnesota and Iowa, the native northern tallgrass prairie has declined to less than 1 percent of its original 25 million acres (10.1 million hectares).

Through an integrated ecosystem approach, the Service, with its partners, proposes to protect and restore fish and wildlife habitats through holistic management strategies using a wide variety of tools, and techniques. The Service proposes to participate in public and private partnerships at many levels, complementing other prairie projects such as those of the Iowa County Conservation Boards, Iowa and Minnesota Departments of Natural Resources, the Nature Conservancy, and others.

The Service will hold 10 open houses from 3:00 to 7:00 p.m. at the following locations and dates: (1) Nobles County