

geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in the proposed labeling, the content and format for geriatric labeling supplements, and the applicability of user fees to geriatric labeling supplements.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Mary E. Ortuzar, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6740; or Toni Stifano, Center for Biologics Evaluation and Research (HFM-600), 1401 Rockville Pike, Rockville, MD 20852, 301-827-6190.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Content and Format for Geriatric Labeling." This guidance has been developed in response to a final rule that published in the **Federal Register** of August 27, 1997 (62 FR 45313), establishing, in the "Precautions" section of prescription drug labeling, a subsection on the use of drugs in elderly or geriatric patients (aged 65 years or over) (§ 201.57(f)(10) (21 CFR 201.57(f)(10))). A draft guidance by the same name was made available for comment by a notice published in the **Federal Register** of January 21, 1999 (64

FR 3302). This guidance incorporates minor revisions based on comments the agency received on the draft guidance. The final guidance makes clear that the application holder is responsible for submitting a supplement to request the omission of the "Geriatric use" subsection or to request an alternative statement and for providing the reasons supporting the request.

The geriatric labeling regulation recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in the elderly that are significantly different from those produced in younger patients. Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age and the significant use of medications by this age group.

This guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs (§ 201.57(f)(10)(i) through (f)(10)(vi)) that outline various options for statements in the "Geriatric use" subsection, based on the type of information available and the interpretation of that information. The guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi) and provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling supplements, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the guidance document.

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 the content and format of geriatric labeling. 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, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above).

Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance 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 at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>.

Dated: September 28, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-24945 Filed 10-4-01; 8:45 am]

**BILLING CODE 4160-01-S**

**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 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 listed at the end, and will be omitted from the monthly listing thereafter.

This Notice is also available on the internet at the following websites: <http://workplace.samhsa.gov>; <http://www.drugfreeworkplace.gov>; and <http://www.health.org/workplace>.

**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, Fax: (301) 443-3031.

#### 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, 414-328-7840/800-877-7016 (Formerly: Bayshore Clinical Laboratory)
- ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 716-429-2264
- Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901-794-5770/888-290-1150
- Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400
- 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
- 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 Laboratory Partners, LLC, 129 East Cedar St., Newington, CT 06111, 860-696-8115 (Formerly: Hartford Hospital Toxicology Laboratory)
- 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, Building 38-H, 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 31602, 912-244-4468
- DrugProof, Division of Dynacare, 543 South Hull St., Montgomery, AL 36103, 888-777-9497/334-241-0522 (Formerly: Alabama Reference Laboratories, Inc.)
- DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206-386-2672/800-898-0180 (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,<sup>1</sup> 14940-123 Ave., Edmonton, Alberta, Canada T5V 1B4, 780-451-3702/800-661-9876
- ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662-236-2609
- Express Analytical Labs, 1301 18th Ave., NW., Suite 110, Austin, MN 55912, 507-437-7322
- Gamma-Dynacare Medical Laboratories,<sup>1</sup> A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519-679-1630
- General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823 (Formerly: Laboratory Specialists, Inc.)
- LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-728-4064 (Formerly: Center for Laboratory Services, a Division of LabOne, 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, 10788 Roselle Street, San Diego, CA 92121, 800-882-7272 (Formerly: Poisonlab, Inc.)
- Laboratory Corporation of America Holdings, 1120 Stateline Road West, Southaven, MS 38671, 866-827-8042/800-233-6339 (Formerly: LabCorp Occupational Testing Services, Inc., MedExpress/National Laboratory Center)
- Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734/800-331-3734
- MAXXAM Analytics Inc.,<sup>1</sup> 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 43699, 419-383-5213
- MedTox Laboratories, Inc., 402 W. County Rd. 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, Minnesota 55417, 612-725-2088
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515
- Northwest Drug Testing, a division of NWT Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 801-293-2300/800-322-3361 (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.)
- One Source Toxicology Laboratory, Inc., 1705 Center Street, Deer Park, TX 77536, 713-920-2559 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)
- Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440-0972, 541-687-2134
- Pacific Toxicology Laboratories, 6160 Variel Ave., Woodland Hills, CA 91367, 818-598-3110/800-328-6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)
- Pathology Associates Medical Laboratories, 11604 E. Indiana Ave., Spokane, WA 99206, 509-926-2400/800-541-7891
- PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817-215-8800 (Formerly: Harris Medical Laboratory)
- Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913-339-0372/800-821-3627
- Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)
- Quest Diagnostics Incorporated, 4444 Giddings Road, Auburn Hills, MI 48326, 248-373-9120/800-444-0106 (Formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath, CORNING Clinical Laboratories)
- Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800-842-6152 (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)
- Quest Diagnostics Incorporated, 801 East Dixie Ave., Suite 105A, Leesburg, FL 34748, 352-787-9006 x4343 (Formerly: SmithKline Beecham Clinical Laboratories, Doctors & Physicians Laboratory)
- Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610-631-4600/

877-642-2216 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800-669-6995/847-885-2010 (Formerly: SmithKline Beecham Clinical Laboratories, International Toxicology Laboratories)

Quest Diagnostics Incorporated, 7470 Mission Valley Rd., San Diego, CA 92108-4406, 619-686-3200/800-446-4728 (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, 7600 Tyrone Ave., Van Nuys, CA 91405, 818-989-2520/800-877-2520 (Formerly: SmithKline Beecham Clinical Laboratories)

Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804-378-9130

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, 219-234-4176

Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602-438-8507/800-279-0027

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

Universal Toxicology Laboratories (Florida), LLC, 5361 NW 33rd Avenue, Fort Lauderdale, FL 33309, 954-717-0300, 800-522-0232 x419 (Formerly: Integrated Regional Laboratories, Cedars Medical Center, Department of Pathology)

University Toxicology Laboratories, LLC, 9930 W. Highway 80, Midland, TX 79706, 915-561-8851/888-953-8851

US Army Forensic Toxicology Drug Testing Laboratory, Fort Meade, Building 2490 Wilson Street, Fort George G. Meade, MD 20755-5235, 301-677-7085

<sup>1</sup> 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 process. 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**, July 16, 1996) as meeting the minimum standards of the "Mandatory Guidelines for Workplace Drug Testing" (59 FR, June 9, 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 Office, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 01-25051 Filed 10-4-01; 8:45 am]

**BILLING CODE 4160-20-M**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4644-N-40]

### Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**DATES:** October 5, 2001.

**FOR FURTHER INFORMATION CONTACT:** Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708-1234; TTY number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

**SUPPLEMENTARY INFORMATION:** In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No 88-2503-0G (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no

additional properties have been determined suitable or unsuitable for this week.

Dated: September 27, 2001.

**John D. Garrity,**

*Director, Office of Special Needs Assistance Programs.*

[FR Doc. 01-24656 Filed 10-4-01; 8:45 am]

**BILLING CODE 4210-29-M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### Notice of Availability of the Draft Environmental Impact Statement/ Environmental Impact Report for the Proposed Teayawa Energy Center, Riverside County, CA

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public that the Bureau of Indian Affairs (BIA) intends to file a draft Environmental Impact Statement /Environmental Impact Report (DEIS/EIR) for the proposed Teayawa Energy Center to be constructed and operated on 41.5 acres of the Torres Martinez Indian Reservation in Riverside County, California. The purpose of the proposed project is to conjointly help provide for the economic development and progress of the Torres Martinez Desert Cahuilla Indians and for the power needs of southern California. Details on the project location, proposed action and areas of environmental concern are addressed in the DEIS/EIR provided in the **SUPPLEMENTARY INFORMATION** section. This notice also announces a public hearing to receive comments on the DEIS/EIR.

**DATES:** Written comments on the DEIS/EIR must arrive by December 3, 2001. The public hearing will be held on Thursday, October 25, 2001, from 7 p.m. to 10 p.m., or until the last public comment is received.

**ADDRESSES:** You may mail or hand carry written comments to Ronald Jaeger, Regional Director, Pacific Region, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825-1846. Please include your name, return address and the caption, "DEIS/EIR Comments, Teayawa Energy Center, Riverside County, California," on the first page of your written comments.

The public hearing will be held at the Tribal Hall, Torres Martinez Indian Reservation, 66725 Martinez Road, Thermal, California. This hearing will be co-hosted by the BIA and the Torres Martinez Indians.