

Regulatory Applications.” This guidance provides recommendations on the use of exposure-response information in the development of drugs, including therapeutic biologics. The guidance describes: (1) The uses of exposure-response studies in regulatory decisionmaking, (2) the important considerations in exposure-response study designs to ensure valid information, (3) the strategy for prospective planning and data analyses in the exposure-response modeling process, (4) the integration of assessment of exposure-response relationships into all phases of drug development, and (5) the format and content of reports of exposure-response studies.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on study design, data analysis, and regulatory applications of exposure-response relationships. 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Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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 <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2002 Competitive Cycle for the Graduate Psychology Education Program 93.191a

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Graduate Psychology Education Program (GPEP) for Fiscal Year 2002.

Authorizing Legislation: These applications are solicited under section 755(b)(1)(J) of the Public Health Service Act as amended, and the FY 2002 Appropriations Act, Public Law 107-116 which provides \$2 million to support graduate psychology education programs to train health service psychologists in accredited psychology programs.

Purpose: Grants will be awarded to assist eligible entities in meeting the costs to plan, develop, operate, or maintain graduate psychology education programs to train health service psychologists to work with underserved populations including children, the elderly, victims of abuse, the chronically ill or disabled and in areas of emerging needs, which will foster an integrated approach to health care services and address access for underserved populations. The Graduate Psychology Education Program addresses interrelatedness of behavior and health and the critical need for integrated health care services. Funding is available to doctoral programs or doctoral internship programs as defined and accredited by the American Psychological Association (APA). Funding may not be used for post-doctoral residency programs.

Eligible Applicants: Eligible entities are accredited health profession schools, universities, and other public or private nonprofit entities. Each Graduate Psychology Education Program must be accredited by the American Psychological Association (APA). As provided in section 750, to be eligible to receive assistance, the eligible entity must use such assistance in collaboration with two or more disciplines.

Funding Preference: A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories or

groups of applications. This statutory general preference will only be applied to applications that rank above the 20th percentile of applications recommended for approval by the peer review group.

As provided in section 791(a) of the Public Health Service Act, preference will be given to any qualified applicant that: (1) Has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or (2) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings. “High Rate” refers to a minimum of 20 percent of graduates in academic year 1999–2000 or academic year 2000–2001, whichever is greater, who spend at least 50 percent of their worktime in clinical practice in the specified settings.

“Significant Increase in the Rate” means that, between academic years 1999–2000 and 2000–2001, the rate of placing graduates in the specified settings has increased by a minimum of 50 percent.

Estimated Amount of Available Funds: \$1,900,000.

Estimated Number of Awards: 15–19.

Estimated Average Size of Each Award: \$100,000–\$130,000.

Estimated Funding Period: One year.

Application Requests, Availability, Date and Addresses: Application materials will be available for downloading via the Web on March 29, 2002. Applicants may also request a hardcopy of the application material by contacting the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland, 20879, by calling at 1-877-477-2123, or by fax at 1-877-477-2345. In order to be considered for competition, applications must be received by mail or delivered to the HRSA Grants Application Center by no later than May 22, 2002. Applications received after the deadline date may be returned to the applicant and not processed.

Projected Award Date: August 30, 2002.

FOR FURTHER INFORMATION CONTACT: LCDR Young Song, Division of State, Community and Public Health, Bureau of Health Professions, HRSA, Room 8C-09, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; or e-mail at ysong@hrsa.gov. Telephone number is (301) 443-3353.

Additional Information: A Technical Assistance Videoconference Workshop is being planned for sometime in April, 2002. Detailed information regarding this workshop will be in the application

materials, and on the HRSA and APA Web site.

Dated: March 26, 2002.

Elizabeth M. Duke,
Administrator.

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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 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 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 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>.

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)
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 *, 14940-123 Ave. Edmonton, Alberta, Canada T5V 1B4, 780-451-3702/800-661-9876

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, Oxford, MS 38655, 662-236-2609

Express Analytical Labs, 3405 7th Avenue, Suite 106, Marion, IA 52302, 319-377-0500

Gamma-Dynacare Medical Laboratories *, 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,