DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Antitumor Macrocyclic Lactones, Compositions and Methods of Use

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in International Patent Application PCT/US98/15011, all related foreign and domestic patents and patent applications, entitled “Antitumor Macrocyclic Lactones, Compositions and Methods of Use” (DHHS Ref. No. E–244–1997/0), and in International Patent Application PCT/US90/05582, all related foreign and domestic patents and patent applications, entitled “Vacuolar-Type (H+)–ATPase Inhibiting Compounds, Compositions, And Use Thereof” (DHHS Ref. No. E–244–1997/3), to Reata Discovery, Inc., located in Dallas, TX. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human therapeutics for the treatment of cancer.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before November 2, 2004 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: George G. Pipia, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; and e-mail: pipia@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The present inventions include macrocyclic lactones, and specifically salicylhalamides and related compounds, which are among the classes of compounds identified from biological sources. The NIH licensee for this technology might have some obligations to the source-country of the biological material. The present inventions further provide a method of preventing or treating cancer, which comprises administration to a patient an effective anticancer amount of at least one compound of the present invention. Furthermore, these compounds act as vacular-type (H+)–ATPase inhibitors and can possibly be useful for the treatment of osteoporosis, development of drug resistance in tumor cells, Alzheimer’s disease, glaucoma, abnormal urinary acidification and treatment or prevention of viral infections (e.g., baculoviruses and retroviruses).

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.


Steven M. Ferguson,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–20093 Filed 9–2–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Suspension of a Laboratory Which No Longer Meets 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 routinely publishes a list of laboratories in the Federal Register that are currently certified to meet standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29925) dated June 9, 1994.

This notice informs the public that the following laboratory’s certification is suspended because extensive fire damage that occurred on July 9, 2004, has prevented the laboratory from testing specimens and fully participating in the National Laboratory Certification Program: Gamma-Dynacare Medical Laboratories, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4.
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 (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the Federal Register on April 11, 1988 (53 FR 11970), and revised in the Federal Register on June 9, 1994 (59 FR 29908), and on September 30, 1997 (62 FR 51118). 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 Mandatory Guidelines.

If any laboratory has withdrawn from HHS National Laboratory Certification Program (NLCP) 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 http://workplace.samhsa.gov and http://www.drugfreeworkplace.gov.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTAL INFORMATION: The Mandatory Guidelines 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 that 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 Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

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

- ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227; 414–328–7840/800–377–7016 (Formerly: Bayshore Clinical Laboratory).
- 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).
- Diagnostic Services Inc., dba DSI, 12700 Westlinks Dr., Fort Myers, FL 33913; 239–561–8200/800–735–5416.
- Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602; 229–671–2281.
- DrugProof, Division of Dynacare Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104; 206–386–2661/800–988–0180 (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).
- DrugScan, Inc., P.O. Box 2969, 1119 Meams Rd., Warsaw, PA 18974; 610–674–9310.
- General Medical Laboratories, 36 South Brooks St., Madison, WI 53715; 608–267–6225.
- 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; 913–888–3927/800–873–8845 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.).
- Laboratory Corporation of America Holdings, 7207 N. Gessner Rd., Houston, TX 77040; 713–856–8288/800–800–2387.
- Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869; 906–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).
- Laboratory Corporation of America Holdings, 10788 Roselle St., San Diego, CA 92121; 800–882–7272 (Formerly: Poisonlab, Inc.).
- Laboratory Corporation of America Holdings, 1120 Stateline Rd. 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; 715–379–3734/800–331–3734.
- MAXXAM Analytics Inc., 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8; 905–817–5700 (Formerly: NOVAMANN (Ontario) Inc.).