

93.878, 93.892, 93.893. National Institutes of Health, HHS)

Dated: March 29, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-7503 Filed 4-1-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Use of Inhibitors of 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase as a Modality in Cancer Therapy**

**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 U.S. Patent 6,040,334 issued March 21, 2000, entitled "Use of Inhibitors of 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase as a Modality in Cancer Therapy" (DHHS Reference No. E-146-1992/0), and all related foreign patents/patent applications, to Bionaut Pharmaceuticals, Inc., which is located in Cambridge, MA. 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 pharmaceutical use of inhibitors of 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase as anti-cancer agents.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 1, 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; e-mail: [pipiag@mail.nih.gov](mailto:pipiag@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The invention provides a method for treating mammalian adenocarcinomas and sarcomas comprising administration of an effective amount of an inhibitor of HMG Co-A or homologues of the inhibitor. Adenocarcinoma is known to afflict the prostate, stomach, lung, breast, and colon, as well as other sites. An example of a sarcoma within the meaning of the present invention is Ewing's sarcoma, which is a medullary bone tumor typically attacking the long bones.

Examples of compounds useful in the present invention are lovastatin and simvastatin as well as their homologues. Also included are compounds classified as HMG Co-A inhibitors, as well as their homologues or analogues. Generally, these HMG Co-A inhibitors are known to lower serum cholesterol in humans. However, the present invention is not so limited. That is, an inhibitor of HMG Co-A or one of its homologues may work in the method of the present invention without necessarily lowering serum cholesterol. The invention focuses not on the compound's ability to lower cholesterol, but rather on the compound's ability to treat selected cancers, such as adenocarcinomas of the prostate, stomach, lung, breast, and colon and certain sarcomas such as Ewing's sarcoma. Typically, the oral route is preferred.

Also provided by the invention is a method of reducing prostate specific antigen (PSA) levels in a patient having prostatic adenocarcinoma comprising administration of an effective amount of a compound which is an inhibitor of HMG Co-A or a homologue of such inhibitor. The invention also includes a method of reducing PSA in conjunction with another treatment modality.

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.

Dated: March 24, 2004.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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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 (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, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301-443-6014 (voice), 301-443-3031 (fax).

**SUPPLEMENTARY INFORMATION:** The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 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, 414-328-7840/800-877-7016, (Formerly: Bayshore Clinical Laboratory).
- ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264.
- 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.
- 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 Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215-2802, 800-445-6917, Diagnostic Services Inc., dba DSI, 12700 Westlinks Dr., Fort Myers, FL 33913, 239-561-8200/800-735-5416.
- DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206-386-2661/800-898-0180, (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\*, 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876.
- ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662-236-2609.
- Express Analytical Labs, 3405 7th Ave., 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, 608-267-6225.
- 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, 908-526-2400/800-437-4986, (Formerly: Roche Biomedical Laboratories, Inc.).
- Laboratory Corporation of America Holdings, 1904 Alexander Dr., 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 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, 715-389-3734/800-331-3734.
- MAXXAM Analytics Inc.\*, 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905-890-2555, (Formerly: NOVAMANN (Ontario) Inc.).
- 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 Dr., Minneapolis, MN 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 S., Salt Lake City, UT 84124, 801-293-2300/800-322-3361, (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.).
- One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774, (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, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).
- Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891 x8991.
- PharmChem Laboratories, Inc., 4600 N. Beach, Haltom City, TX 76137, 817-605-5300, (Formerly: PharmChem Laboratories, Inc., Texas Division; 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, 770-452-1590/800-729-6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800-824-6152, (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750 (Formerly: Associated Pathologists Laboratories, Inc.).
- 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, 7600 Tyrone Ave., Van Nuys, CA 91405, 818-989-2520/800-877-2520, (Formerly: SmithKline Beecham Clinical Laboratories).

Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130.

Sciteck Clinical Laboratories, Inc., 317 Rutledge Rd., Fletcher, NC 28732, 828-650-0409.

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, 574-234-4176 x276.

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, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573-882-1273.

Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166, 305-593-2260.

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

\*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. HHS, with the HHS' 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, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR

51118). After receiving DOT certification, the laboratory will be included in the monthly list of HHS certified laboratories and participate in the NLCP certification maintenance program.

**Anna Marsh,**

*Executive Officer, SAMHSA.*

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**BILLING CODE 4160-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Request for Applications for State Incentive Grants for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders (COSIG)

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of request for applications for State Incentive Grants for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders (COSIG).

**Authority:** Sections 509 and 520A of the Public Health Service Act.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), and Center for Mental Health Services (CMHS), are accepting applications for Fiscal Year 2004 grants to develop and enhance the infrastructure of States and their treatment service systems to increase the capacity to provide accessible, effective, comprehensive, coordinated/integrated, and evidence-based treatment services to persons with co-occurring substance abuse and mental health disorders, and their families. COSIG also provides an opportunity to participate in an evaluation of the feasibility, validity and reliability of the proposed co-occurring performance measures for the future Performance Partnership Grants (PPGs), and to participate in a national evaluation of the COSIG program.

**DATES:** Applications are due on June 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** For questions on program issues contact: Richard E. Lopez, J.D., PhD., SAMHSA/CSAT/DSCA, 5600 Fishers Lane, Rockwall II, Suite 8-147, Rockville, MD 20857, Phone: (301) 443-7615; E-Mail: [rlopez@samhsa.gov](mailto:rlopez@samhsa.gov); or Lawrence Rickards, PhD., SAMHSA/CMHS/DSSI, 5600 Fishers Lane, Room 11C-05, Rockville, MD 20857; Phone: 301-443-3707; E-mail : [rickard@samhsa.gov](mailto:rickard@samhsa.gov).

For questions on grants management issues contact: Kathleen Sample, SAMHSA/Division of Grants Management, 5600 Fishers Lane, Suite 630, Rockville, MD 20857, Phone: (301) 443-9667; E-mail: [ksample@samhsa.gov](mailto:ksample@samhsa.gov).

#### SUPPLEMENTARY INFORMATION:

#### State Incentive Grants for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders (SM 04-012) (Initial Announcement)

Catalog of Federal Domestic Assistance (CFDA) No.: CFDA No. 93.243.

#### Key Dates

**Application Deadline.**—Applications are due by June 8, 2004.

**Intergovernmental Review (E.O. 12372).**—Letters from State Single Point of Contact (SPOC) are due August 7, 2004.

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#### I. Funding Opportunity Description

##### 1. Introduction

As authorized under Section 509 and 520A of the Public Health Services Act, the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), and Center for Mental Health Services (CMHS), announce the availability of funds for Fiscal Year 2004 grants. These grants will develop and