

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.*

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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