

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: Orally Active Synthetic Estrogens for Fertility Control, Hormone Replacement Therapy, and Endometriosis**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(1), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the invention embodied in United States Patent No. 5,554,603, issued September 10, 1996, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-US-01); PCT Application No. PCT/US94/10393, filed September 15, 1994, now expired, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-PCT-02); Australian Patent No. 700576, issued April 22, 1999, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-AU-03); Canadian Patent No. 2171740, issued July 26, 2005, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-CA-04); European Patent No. 719276, issued November 26, 1997, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-EP-05) and validated in Austria, Switzerland, Germany, Denmark, Spain, France, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal, Sweden, Belgium, and Great Britain; and Japanese Patent No. 3993228, issued August 3, 2007, entitled "Orally Active Derivatives of 1, 3, 5(10)-Estratriene" (HHS Ref. No. E-137-1993/0-JP-06) to Evestra, Inc., having a place of business in San Antonio, Texas. The patent rights in this invention have been assigned to the United States of America.

The contemplated exclusive license territory may be worldwide, and the field of use may be limited to the use of CDB-3701 (11 $\beta$ , 17 $\beta$ -dinitratoestradiol 3-acetate) for all indications where estrogen is prescribed as a treatment, including fertility control, hormone replacement therapy ("HRT"), and endometriosis.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of

Technology Transfer on or before June 1, 2009 will be considered.

**ADDRESSES:** Requests for copies of the patents, inquiries, comments, and other materials relating to the contemplated license should be directed to: Tara L. Kirby, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301-435-4426; Facsimile: 301-402-0220; E-mail: [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The utility of estrogenic substances in the practice of medicine is well documented. Estrogens may be used for the replacement of the natural hormone estradiol in hypogonadism, and following the removal of the ovaries or cessation of ovarian activity during menopause. They are also widely employed as a component of oral contraceptives. However, available orally-active synthetic estrogens are associated with a number of potential side effects, including cancer, blood clots, heart attack, elevated blood pressure, and reduced glucose tolerance.

This technology relates to a family of novel, active estrogens that are nitrate esters of estradiol. These nitrate esters possess enhanced estrogenic activity following oral administration and lack a 17-ethynyl alcohol, which has been implicated in many side effects attributed to other synthetic estrogens. It is anticipated that these esters could be used in all instances where estrogen is prescribed as a treatment.

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 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the prospective 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 in response 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, 2009.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5307-N-01]

**Notice of Web Site Availability: Allocations, Application Procedures and Requirements for Homelessness Prevention and Rapid Re-Housing Program Grantees Under the American Recovery and Reinvestment Act of 2009**

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

**ACTION:** Notice.

**SUMMARY:** Through this notice, HUD announces the availability on its Web site of the allocation formula, allocation amounts, list of grantees, statutory and regulatory program requirements, submission deadlines, and other requirements for the Homelessness Prevention and Rapid Re-Housing Program (HPRP) authorized by Title XII of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-05, approved February 17, 2009). HPRP funding is focused on providing short- and medium-term rental assistance to individuals and families who are currently in housing, but at risk of becoming homeless, and individuals and families who are homeless. Approximately \$1.489 billion will be allocated for these purposes to states, metropolitan cities, urban counties and territories. State sub-grantees and non-profit sub-grantees are also eligible to receive HPRP funds from grantees. The notice establishing the program and application requirements for these funds, allocation information, and eligibility criteria is available on the HUD Web site at: <http://www.hud.gov/recovery/homeless-prevention.cfm>.

**FOR FURTHER INFORMATION CONTACT:** Ann Marie Oliva, Director, Office of Special Needs Assistance Programs, Office of Special Needs Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street, SW., Room 7262, Washington DC 20410-3000; telephone 1-800-998-9999. Hearing- or speech-impaired individuals may access the voice telephone number listed above by calling the toll-free