

**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.*

[FR Doc. E9-7210 Filed 3-30-09; 8:45 am]

**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

Federal Information Relay Service during working hours at 800-877-8339.

Dated: March 25, 2009.

**Nelson R. Bregón,**

*General Deputy Assistant Secretary for Community Planning and Development.*

[FR Doc. E9-7182 Filed 3-30-09; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

[Docket No. MMS-2008-OMM-0041]

#### **MMS Information Collection Activity: 1010-0048 Geological and Geophysical (G&G) Explorations of the OCS, Extension of a Collection; Comment Request**

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Notice of extension of an information collection (1010-0048).

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), MMS is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR part 251, Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf.

**DATES:** Submit written comments by June 1, 2009.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Blundon, Regulations and Standards Branch at (703) 787-1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulation and form that require the subject collection of information.

**ADDRESSES:** You may submit comments by either of the following methods listed below.

- *Electronically:* Go to <http://www.regulations.gov>. Under the tab More Search Options, click Advanced Docket Search, then select Minerals Management Service from the agency drop-down menu, then click submit. In the Docket ID column, select MMS-2008-OMM-0041 to submit public comments and to view supporting and related materials available for this rulemaking. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's User Tips link. The MMS will post all comments.

- Mail or hand-carry comments to the Department of the Interior, Minerals Management Service, Attention: Cheryl Blundon, 381 Elden Street, MS-4024, Herndon, Virginia 20170-4817. Please reference Information Collection 1010-0048 in your subject line and mark your message for return receipt. Include your name and return address in your message text.

#### **SUPPLEMENTARY INFORMATION:**

*Title:* 30 CFR Part 251, Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf.

*Form(s):* MMS-327.

*OMB Control Number:* 1010-0048.

*Abstract:* The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

The OCS Lands Act (43 U.S.C. 1340) also states that "any person authorized by the Secretary may conduct geological and geophysical explorations in the [O]uter Continental Shelf, which do not interfere with or endanger actual operations under any lease maintained or granted pursuant to this OCS Lands Act, and which are not unduly harmful to aquatic life in such area." The section further requires that permits to conduct such activities may only be issued if it is determined that the applicant is qualified; the activities are not polluting, hazardous, or unsafe; they do not interfere with other users of the area; and do not disturb a site, structure, or object of historical or archaeological significance. Applicants for permits are required to submit form MMS-327 to provide the information necessary to evaluate their qualifications.

The OCS Lands Act (43 U.S.C. 1352) further requires that certain costs be reimbursed to the parties submitting required G&G information and data. Under the OCS Lands Act, permittees are to be reimbursed for the costs of reproducing any G&G data required to be submitted. Permittees are to be reimbursed also for the reasonable cost

of processing geophysical information required to be submitted when processing is in a form or manner required by the Director of MMS and is not used in the normal conduct of the business of the permittee.

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104-133, 110 Stat. 1321, April 26, 1996), and the Office of Management and Budget (OMB) Circular A-25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's (DOI) implementing policy, the Minerals Management Service (MMS) is required to charge the full cost for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those that accrue to the public at large. The G&G permits are subject to cost recovery, and MMS regulations specify the filing fee for the application.

Regulations at 30 CFR part 251 implement these statutory requirements. We use the information to ensure there is no environmental degradation, personal harm or unsafe operations and conditions, damage to historical or archaeological sites, or interference with other uses; to analyze and evaluate preliminary or planned drilling activities; to monitor progress and activities in the OCS; to acquire G&G data and information collected under a Federal permit offshore; and to determine eligibility for reimbursement from the government for certain costs. The information is necessary to determine if the applicants for permits or filers of notices meet the qualifications specified by the OCS Lands Act. The MMS uses information collected to understand the G&G characteristics of oil- and gas-bearing physiographic regions of the OCS. It aids the Secretary in obtaining a proper balance among the potentials for environmental damage, the discovery of oil and gas, and adverse impacts on affected coastal states. Information from permittees is necessary to determine the propriety and amount of reimbursement.

We will protect information from respondents considered proprietary according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), the Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1733), and under regulations at 30 CFR parts 250, 251, and 252.

No items of a sensitive nature are collected. Responses are mandatory.

*Frequency:* On occasion, annual; and as specified in permits.