

Dated: January 10, 2014.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-00672 Filed 1-15-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Start-Up Exclusive Patent License Agreement: Treatment of Inflammatory Bowel Disease (IBD), Including Ulcerative Colitis and Crohn's Disease

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

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License Agreement to Paris Therapeutics, a company having a place of business in Santee, CA, to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application. No. 61/488,671, filed 20 May 2011 HHS Ref. No.: E-073-2011/0-US-01 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
2. PCT Application No. PCT/US2012/028926, filed 13 March 2012 HHS Ref. No.: E-073-2011/1-PCT-02 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
3. U.S. Patent Application No. 13/419,203, filed 13 March 2012 HHS Ref. No.: E-073-2011/1-US-01 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
4. Australian Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 26 November 2013 HHS Ref. No.: E-073-2011/1-AU-03 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
5. Canadian Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 19 November 2013 HHS Ref. No.: E-073-2011/1-CA-04 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
6. European Patent Application No. 12790157.7, filed 14 November 2013 HHS Ref. No.: E-073-2011/1-EP-05 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
7. Japanese Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 20 November 2013 HHS Ref. No.: E-073-2011/1-JP-06 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
8. Korean Patent Application claiming priority to PCT/US2012/028926, application number not available at this time, filed 18 December 2013 HHS Ref. No.: E-073-2011/1-KR-07 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
9. Mexican Patent Application No. MX/a/2013/013329, filed 14 November 2013 HHS Ref. No.: E-073-2011/1-MX-08 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology and Antibodies Thereof Inventors: Richard Siegel (NIAMS), Francoise Meylan (NIAMS), and Yun-Jeong Song (NIAMS)
10. U.S. Provisional Patent Application No. 60/879,668, filed 10 January 2007, now expired, HHS Ref. No.: E-011-2007/0-US-01 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology Inventors: Richard Siegel (NIAMS) and Francoise Meylan (NIAMS)
11. U.S. Patent Application No. 11/972,395, filed 10 January 2008, now abandoned, HHS Ref. No.: E-011-2007/0-US-02 Titled: Blockade of TL1A-DR3 Interactions to Ameliorate T Cell Mediated Disease Pathology Inventors: Richard Siegel (NIAMS) and Francoise Meylan (NIAMS)

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide, and the field of use may be limited to "Antibodies against TL1A for the Treatment of Inflammatory Bowel Disease (IBD), including Ulcerative Colitis and Crohn's Disease."

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before January 31, 2014 will be considered.

**ADDRESSES:** Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License Agreement should be directed to: Jaime M. Greene, M.S., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5559; Facsimile: (301) 402-0220; Email: [greenajaime@mail.nih.gov](mailto:greenajaime@mail.nih.gov). A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology concerns anti-mouse TNF family ligand Tumor Necrosis Factor (ligand) Superfamily, Member 15 (TL1A) and anti-human TL1A monoclonal antibodies and the hybridoma cell lines generating these antibodies, as well as methods of treating autoimmune inflammatory diseases by blocking the interaction between TL1A and Tumor Necrosis Factor Receptor superfamily, Member 25 (DR3). This technology may be useful for the development of diagnostics and therapeutics for autoimmune inflammatory disease.

The prospective Start-Up Exclusive Patent License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-Up Exclusive Patent License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent License Agreement. 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: January 9, 2014.

**Richard U. Rodriguez,**

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

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## DEPARTMENT OF THE INTERIOR

### Bureau of Safety and Environmental Enforcement (BSEE)

[Docket ID BSEE-2013-0013; OMB Control Number 1014-0011; 134E1700D2 EEEE50000 ET1SF0000.DAQ000]

#### Information Collection Activities: Platforms and Structures; Proposed Collection; Comment Request

**ACTION:** 60-day notice.

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE 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 a renewal to the paperwork requirements in the regulations under Subpart I, *Platforms and Structures*.

**DATES:** You must submit comments by March 17, 2014.

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

- *Electronically:* go to <http://www.regulations.gov>. In the entry titled *Enter Keyword or ID*, enter BSEE-2013-0013 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.

- *Email:* [nicole.mason@bsee.gov](mailto:nicole.mason@bsee.gov). Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 381 Elden Street, HE3313; Herndon, Virginia 20170-4817. Please reference ICR 1014-0011 in your comment and include your name and return address.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mason, Regulations and Standards Branch at (703) 787-1605 to request additional information about this ICR.

#### SUPPLEMENTARY INFORMATION:

*Title:* 30 CFR part 250, Subpart I, *Platforms and Structures*.

*OMB Control Number:* 1014-0011.

*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 to prescribe rules and regulations necessary for the administration of the leasing provisions of the Act related to the mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-way, or a right-of-use and easement. 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.

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

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 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 implementing policy, BSEE 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. Several requests for approval required in Subpart I are subject to cost recovery,

and BSEE regulations specify service fees for these requests.

Regulations implementing these responsibilities are among those delegated to BSEE to ensure that operations in the OCS will meet statutory requirements; provide for safety and protection of the environment; and result in diligent exploration, development, and production of OCS leases. This ICR addresses the regulations at 30 CFR part 250, Subpart I, and the associated supplementary notices to lessees and operators (NTLs) intended to provide clarification, description, or explanation of these regulations.

We use the information to determine the structural integrity of all OCS platforms and floating production facilities and to ensure that such integrity will be maintained throughout the useful life of these structures. We use the information to ascertain, on a case-by-case basis, that the fixed and floating platforms and structures are structurally sound and safe for their intended use to ensure safety of personnel and prevent pollution. More specifically, we use the information to:

- Review data concerning damage to a platform to assess the adequacy of proposed repairs.
- Review applications for platform construction (construction is divided into three phases—design, fabrication, and installation) to ensure the structural integrity of the platform.
- Review verification plans and third-party reports for unique platforms to ensure that all nonstandard situations are given proper consideration during the platform design, fabrication, and installation.
- Review platform design, fabrication, and installation records to ensure that the platform is constructed according to approved applications.
- Review inspection reports to ensure that platform integrity is maintained for the life of the platform.

We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2), and under regulations at 30 CFR 250.197 and 30 CFR 252, which addresses disclosure of data and information to be made available to the public. No items of a sensitive nature are collected. Responses are mandatory or are required to obtain a benefit.

*Frequency:* On occasion, weekly, monthly, semi-annually, annually, and as a result of situations encountered depending upon the requirements.

*Description of Respondents:* Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.