DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Option Exclusive License: The Development of Liposomal Therapeutic Agents for the Treatment of Human Epithelial Cancers and Liposarcomas

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)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to ZoneOne Pharma, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following U.S. Patent (and all foreign counterparts): Serial No. 6,890,917 entitled, “Geldanamycin Derivative and Method of Treating Cancer Using Same” [HHS Ref. E–050–2000/0/US–15]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

- In vivo data available (animal)
- **Inventors:** Menghai Xia, Ruili Huang, Christopher P. Austin (all of NCATS)


**Licensing Contact:** Sabarni Chatterjee, Ph.D., MBA; 301–435–5587; chatterjees@email.nih.gov.

**Collaborative Research Opportunity:** The National Center for Advancing Translational Sciences, Division of Pre-Clinical Innovation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Combination Chemotherapeutics for the Treatment of Chordoma. For collaboration opportunities, please contact Lili M. Portilla, MPA at lili@nih.gov.

Dated: March 8, 2013.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, 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) 435–5560; Facsimile: (301) 402–0220; Email: mccuepat@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:** This invention concerns 17–DMAG, the first water-soluble analog of 17–AAG, a less toxic and more stable analog of the antitumor antibiotic geldanamycin.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation license, and a subsequent exclusive commercialization license, may be granted unless 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 within fifteen (15) days from the date of this published notice.

Complete 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 evaluation option 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.

DEPARTMENT OF HOMELAND SECURITY

Chemical Facility Anti-Terrorism Standards (CFATS)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 30-day notice and request for comments; Extension of Information Collection Request: 1670–0014.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), Infrastructure Security Compliance Division (ISCD) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The Department previously published this ICR in the Federal Register on December 17, 2012, for a 60-day public comment period. In this notice, NPPD is responding to one comment and is soliciting public comments concerning the extension of Information Collection Request, Chemical Facility Anti-Terrorism Standards (CFATS) for an additional 30 days.

DATES: Comments are encouraged and will be accepted until April 17, 2013. This process is conducted in accordance with 5 CFR 1320.10.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to OMB Desk Officer, Department of Homeland Security, National Protection and Programs Directorate. Comments must be

CFATS is the Department’s regulations under Section 550 governing security at high-risk chemical facilities. See 6 CFR part 27. CFATS represents a national-level effort to minimize terrorism risk to such facilities. Its design and implementation balance maintaining economic vitality with security facilities and their surrounding communities. In collaboration with the private sector and other stakeholders, the Department designed the regulations to take advantage of protective measures already in place and to allow facilities to employ a wide range of tailored measures to satisfy the regulations’ Risk-Based Performance Standards (RBPS).

The instruments within this collection will be used to manage the CFATS program.

Response to Comment Submitted During 60-Day Comment Period: The Department received a comment suggesting that in the 60-day notice, the Department incorrectly calculated the burden estimates associated with the instrument “Request for a Technical Correction.” The commenter assumed that the number of responses per respondent for this instrument was one. In fact, the Department estimated in the current Information Collection, which expires on March 31, 2013, that each respondent will on average respond 1.5 times. This assumption was carried over into the burden estimates used by the Department in the 60-day notice but not made explicit. The total annual burden for this instrument is calculated as follows [0.25 hours x 185 respondents x 1.5 responses per respondent], which equals 69.37 hours. The Department did not revise the burden estimates for this instrument.

Therefore, for this instrument and the other instruments in this 30-day notice the Department will continue to rely on the analysis and resulting burden estimates in the 60-day notice.

Analysis


Title: Chemical Facility Anti-Terrorism Standards (CFATS).

OMB Number: 1670–0014.

Instrument: Request for Redetermination.

Frequency: On occasion/Other.

Affected Public: Business or other for-profit.

Number of Respondents: 625 respondents (estimate).

Estimated Time per Respondent: 0.25 hours.

Total Burden Hours: 156.25 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $13,437.

Instrument: Request for an Extension.

Frequency: On occasion/Other.

Affected Public: Business or other for-profit.

Number of Respondents: 185 respondents (estimate).

Estimated Time per Respondent: 0.25 hours.

Total Burden Hours: 46.25 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $3,977.

Instrument: Notification of a New Top Screen.

Frequency: On occasion/Other.

Affected Public: Business or other for-profit.

Number of Respondents: 1250 respondents (estimate).

Estimated Time per Respondent: 0.25 hours.

Total Burden Hours: 468.75 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $40,312.

Instrument: Request for a Technical Consultation.

Frequency: On occasion/Other.

Affected Public: Business or other for-profit.

Number of Respondents: 185 respondents (estimate).

Estimated Time per Respondent: 0.25 hours.

Total Burden Hours: 69.37 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $5,966.
The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), collects the core regulatory data through the portions of the Chemical Security Assessment Tool (CSAT) covered under this collection. For more information about CFATS and CSAT, you may access the Department’s Paperwork Reduction Act burden estimates. The Department has made available on its Web site (www.dhs.gov/chemicalsecurity) updated materials that contain the correct citation.

Response to Comments Submitted During the 60-Day Comment Period

The Department received two comments in response to the Federal Register notices published on December 17, 2012. One comment requested that the Department correct a citation in one of its user guides but did not comment on the Department’s Paperwork Reduction Act burden estimates. The Department has made available on its Web site version 2.8 of DHS Form 9007 which contains the correct citation.