

Independence Avenue SW, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:**

Helen Lamont (202) 260-6075, [helen.lamont@hhs.gov](mailto:helen.lamont@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Council on Alzheimer's Research, Care, and Services meets quarterly to discuss programs that impact people with Alzheimer's disease and related dementias and their caregivers. The Advisory Council makes recommendations to Congress and the Secretary of Health and Human Services about ways to reduce the financial impact of Alzheimer's disease and related dementias and to improve the health outcomes of people with these conditions. The Advisory Council also provides feedback on a National Plan for Alzheimer's disease. On an annual basis, the Advisory Council evaluates the implementation of the recommendations through an updated National Plan. The National Alzheimer's Project Act, Public Law 111-375 (42 U.S.C. 11225), requires that the Secretary of Health and Human Services (HHS) establish the Advisory Council on Alzheimer's Research, Care, and Services. The Advisory Council is governed by provisions of Public Law 92-463 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council consists of 22 members. Ten members are designees from Federal agencies including the Centers for Disease Control and Prevention, Administration for Community Living, Centers for Medicare and Medicaid Services, Indian Health Service, National Institutes of Health, National Science Foundation, Department of Veterans Affairs, Food and Drug Administration, Agency for Healthcare Research and Quality, and the Health Resources and Services Administration. The Advisory Council also consists of 12 non-federal members selected by the Secretary who represent 6 categories of people impacted by dementia: Dementia caregivers (2), health care providers (2), representatives of State health departments (2), researchers with dementia-related expertise in basic, translational, clinical, or drug development science (2), voluntary health association representatives (2), and dementia patient advocates, including an advocate who is currently living with the disease (2). At this time, the Secretary shall appoint one member for the researcher, voluntary health association, healthcare provider, patient advocate, caregiver categories to replace the five members whose terms will end

on September 30th, 2019. After receiving nominations, the Secretary, with input from his staff, will make the final decision, and the new members will be announced soon after. Members shall be invited to serve 4-year terms. The member living with dementia will serve a 2-year term. A member may serve after the expiration of the member's term until a successor has taken office. Members will serve as Special Government Employees.

Dated: May 17, 2019.

**Brenda Destro,**

*Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.*

[FR Doc. 2019-10775 Filed 5-22-19; 8:45 am]

**BILLING CODE 4150-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of an Exclusive Patent License: The Development and Use of a Therapeutic STAT3 Inhibitor, GLG-302, in All Proliferative Diseases, Where STAT3 Is Present**

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

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of 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 the (U.S.) Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to GLG Pharma LLC located in Jupiter, Florida, USA.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before June 7, 2019 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Sidra Ahsan, Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240) 276-5530; Facsimile: (240) 276-5504 Email: [ahsans@mail.nih.gov](mailto:ahsans@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

United States Provisional Patent Application No. 62/481,960, filed April

5, 2017 and entitled "Improved STAT3 Inhibitor Formulation" [HHS Reference No. E-035-2017/0-US-01]; PCT Patent Application No. PCT/US2018/026228, filed April 5, 2018 and entitled "STAT3 Inhibitor Formulation" [HHS Reference No. E-035-2017/0-PCT-02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: "The development and commercialization of a therapeutic STAT3 inhibitor, GLG-302, in all proliferative diseases, where STAT3 is present."

This technology discloses the use of the STAT3 inhibitor GLG-302 with Trizma salts for preclinical anti-cancer and cancer preventive activity. GLG-302 is a proprietary compound developed by GLG Pharma LLC. Trizma salts allow GLG-302 to remain in solution for oral administration. This formulation has been demonstrated to be effective in the modulation of STAT3 signaling and proliferation in normal mammary ductal epithelium, and this formulation has demonstrated mammary cancer preventive efficacy in rat (ER+) and mouse (ER-) models. The technology provides improved sample handling and oral bioavailability suggesting that a therapeutic product derived from this technology would be applicable for the treatment of cancer where STAT3 is present.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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 part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the

Freedom of Information Act, 5 U.S.C. 552.

Dated: May 15, 2019.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2019-10779 Filed 5-22-19; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: Hazardous Waste Worker Training Grantee Data Collection—42 CFR Part 65 (National Institute of Environmental Health Sciences)**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Joseph T. Hughes, Jr., Director, Worker Training Program (WTP), Division of Extramural Research and

Training (DERT), NIEHS, P.O. Box 12233 MD: K3-14, Research Triangle Park, NC 27709 or call non-toll-free number (984) 287-3271 or Email your request, including your address to: *hughes3@niehs.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on March 12, 2019, Vol. 84, No. 48 page 8883 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

*Proposed Collection:* Hazardous Waste Worker Training Grantee Data Collection—42 CFR part 65 (NIEHS), 0925-0348, Expiration Date 03/31/2019 REINSTATEMENT WITHOUT CHANGE, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of

non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In thirty-one years (FY 1987-2018), the NIEHS WTP has successfully supported 20 primary grantees that have trained more than 4.1 million workers across the country and presented over 245,830 classroom and hands-on training courses, which have accounted for over 50 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4 (a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to upload their information into the WTP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards and whether appropriate training is being conducted to support continuation of the grant into subsequent years.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 616.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Information Collection Questionnaire (Data Management System).	Grantee .....	22	2	14	616
Total .....	.....	22	44	.....	616