DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer

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 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license, subject to existing non-exclusive licenses and current non-exclusive license applications under consideration, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/405,668 and PCT Patent Application No. PCT/US2011/057272 and foreign equivalents thereof entitled ''Anti-MAGE–A3 T cell receptors and related materials and methods of use'' (HHS Ref. No. E–236–2010/0); U.S. Provisional Patent Application No. 61/384,931 and PCT Patent Application No. PCT/US2011/051537 and foreign equivalents thereof entitled ''Anti-SSX–2 T cell receptors and related materials and methods of use'' (HHS Ref. No. E–269–2010/0); U.S. Provisional Patent Application No. 61/473,409 entitled ''Anti-epidermal growth factor receptor variant III chimeric antigen receptors and use of same for the treatment of cancer'' (HHS Ref. No. E–148–2011/0); and U.S. Provisional Patent Application No. 61/535,086 entitled ''T cell receptors recognizing HLA–A1- or HLA–Cw7-restricted MAGE–A'' (E–266–2011/0) to Kite Pharma, Inc., which is located in Los Angeles, California. The patent rights in these inventions have been assigned to the United States of America.

Other than license applications submitted as objections to this Notice of Intent to Grant an Exclusive License, no further license applications will be considered for the exclusive field of use set forth below if Kite Pharma, Inc. is granted an exclusive license pursuant to this Notice of Intent to Grant an Exclusive License. The prospective exclusive license territory may be worldwide and the field of use may be limited to the treatment of cancers, which may include brain cancer, breast cancer, colorectal cancer, esophageal cancer, gastric cancer, head and neck cancer, liver cancer, lung cancer, melanoma, multiple myeloma, ovarian cancer, prostate cancer, sarcoma, and urothelial cancer, as claimed in the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 23, 2012 will be considered, in addition to the current non-exclusive applications under consideration, for the prospective license territory and field of use to be granted under the contemplated exclusive patent license.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Samuel E. Bish, 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) 435–5282; Facsimile: (301) 402–0220; Email: *bishse@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The technologies describe T cells engineered to express MAGE–A3, MAGE–A12, or SSX–2 T cell receptors (TCRs) or EGFRvIII chimeric antigen (CARs) and methods of using these engineered T cells to treat and/or prevent cancer. These technologies include the TCR and CAR amino acid sequences, the nucleic acid sequences that encode these compositions, vectors to express the TCRs and CARs, host cells and populations of host cells, such as T cells, that express the compositions, antibodies to the TCRs and CARs, pharmaceutical compositions, and associated methods of detecting, preventing, and treating diseases, such as cancer, with these TCRs and CARs. TCRs and CARs are proteins that recognize antigens, such as cancer antigens, and activate the cells expressing these compositions to destroy the antigen-expressing cell. TCRs consist of two domains, one variable domain that recognizes the antigen and one constant region that helps the TCR anchor to the membrane and transmit recognition signals by interacting with other proteins. CARs are hybrid proteins consisting of a portion of an antibody that recognizes an antigen fused to protein domains that signal to activate the CAR-expressing cell. Therapies utilizing these technologies involve isolating a cancer patient's own T cells to be engineered with the TCR and/or CAR that recognize the tumor antigen(s) expressed on that specific patient's cancer cell. Afterwards, the engineered T cells from the patient are adoptively transferred back into the patient to mediate tumor regression. Personalized adoptive cell transfer therapies developed from these technologies could yield innovative therapeutics for any cancers that express the antigens recognized by these TCRs and CARs.

The prospective exclusive license, subject to current non-exclusive license applications under consideration and any further license applications received as objections to this Notice of Intent to Grant an Exclusive License, will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) 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.

Any additional 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 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.

Dated: January 18, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–1383 Filed 1–23–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2011–0029; OMB No. 1660–0095]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, National Flood Insurance Claims Appeals Process

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management

and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before February 23, 2012.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or email address *FEMA-Information-Collections-Management@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Title: National Flood Insurance Claims Appeals Process.

Type of Collection: Revision of a currently approved information collection.

OMB Number: 1660–0095.

Abstract: The process requires policyholders to submit a written appeal to FEMA (Mitigation Directorate/Risk Insurance Division), in the form of a signed letter explaining the nature of their claim appeal, names and titles of persons contacted, dates of contact, contact information, and details of the contact relevant to their claim appeal. FEMA will review the documentation submitted by the policyholder, conduct any necessary additional investigation, and advise, both the policyholder and the appropriate flood insurance carrier, of its decision regarding the appeal.

Affected Public: Individuals and Households.

Number of Respondents: 1,055.

Estimated Time per Respondent: State, 5 hours; Local, 5 hours; and Tribal 5 hours.

Estimated Total Annual Burden Hours: 2,110 hours.

Frequency of Response: One Time.

John G. Jenkins, Jr.,

Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2012–1312 Filed 1–23–12; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2011–0031; OMB No. 1660–0038]

Agency Information Collection Activities: Submission for OMB Review; Comment Request, Write Your Own (WYO) Company Participation Criteria; New Applicant

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before February 23, 2012.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 1800 South Bell Street, Arlington, VA 20598–3005, facsimile number (202) 646–3347, or email address *FEMA-Information-Collections-Management@dhs.gov*.

SUPPLEMENTARY INFORMATION:

Collection of Information

Title: Write Your Own (WYO) Company Participation Criteria; New Applicant.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0038.

Form Titles and Numbers: None.

Abstract: New insurance companies that seek to participate in the WYO program, as well as former WYO companies seeking to return, must meet standards for WYO Financial Control Plan (approved under OMB Control #1660–0020). Private Insurance Companies and/or public entity risk-sharing organizations wishing to enter or reenter the WYO program must demonstrate the ability to meet the financial requirements. The information allows FEMA to determine the applicant's capability of meeting program goals including marketing of flood insurance, training agents and staff in the program rules, and its capabilities for claims handling and disaster response.

Affected Public: Business of other for-profit.

Estimated Number of Respondents: 5.

Frequency of Response: Once.

Estimated Average Hour Burden per Respondent: Application Process, 7 hours.

Estimated Total Annual Burden Hours: 35 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $2,223.55. There are no annual costs to respondents operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $1,204.

John G. Jenkins, Jr.,

Acting Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2012–1313 Filed 1–23–12; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2007–0008]

National Advisory Council

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.