DATES: Submit either electric or written requests for participation in the pilot project by January 27, 2014.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to *http://www.regulations.gov.* Summit written requests and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1062, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1160, Silver Spring, MD 20993, 301–796–5333, *ronald.fitzmartin@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the 1999 ''Guidance to Industry: Providing Regulatory Submissions in Electronic Format'' FDA recommended that regulatory submissions of clinical data to FDA utilize SAS Institute's open transport called XPORT version 5 format (XPORT). The XPORT format was developed in the late 1980s and there have been no version updates since 1999. XPORT is now considered by many to be an outdated transport technology for transferring data across different hardware and operating systems.

Following a **Federal Register** Notice, FDA held a public meeting on November 5, 2012, entitled ''Regulatory New Drug Review: Solutions for Study Data Exchange Standards.'' The purpose of the public meeting was to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. FDA indicated, in the Notice and at the meeting, based on feedback received at the public meeting and other information sources, it would undertake further requirements analysis in support of expected evaluation projects.

II. Project Participation

FDA envisions several pilot projects conducted to evaluate new transport formats. The purpose of this pilot project is to obtain additional experience with CDISC SDS XML format. A successful pilot may allow CDER and CBER to routinely receive study data that employ CDISC SDS XML format as the transport format once an alternatives analysis is completed. As part of this pilot, FDA would like to have sponsors participate in the preparation and submission of previously submitted study datasets using the SDS XML transport format. Participation in this evaluation will be outside of the regulatory pathway and, as such, will not be used to make regulatory decisions.

FDA expects that the pilot will assess the technical capability of SDS XML to exchange and archive regulatory study data in investigational new drug applications, new drug applications, and biologics licensing applications.

III. Requests for Participation

Requests to participate in the SDS XML pilot project are to be identified with the docket number found in brackets in the heading of this document. Interested persons should include the following information in the request: Contact name, contact phone number, email address, name of the sponsor, address, and license number. Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot project. FDA is seeking a limited number of sponsors (approximately three to five, but no more than six) to participate in this project. The elapsed time duration of the pilot is expected to be approximately 12 months but may be extended as needed. Participants should be willing to provide previously submitted study data using both the SAS XPORT version 5 format and the CDISC SDS XML format.

Dated: November 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28391 Filed 11–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: GMCSF-BclxL-Derived Chimeric Therapeutics for Use in Treatment of Cancer, Neutropenia, CNS Injury and Parkinson's Disease

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, indicates that 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 technology family E–150–2005/0, including U.S. Patent application 11/991,692 [HHS Ref. E–150–2005/0–US–07], PCT Application PCT/US06/35070 [HHS Ref. E–150–2005/0–PCT–02] and foreign equivalents thereof, entitled ''Methods and Compositions for Inhibiting Cell Death or Enhancing Cell Proliferation'', to Medicenna Therapeutics, Inc., located in Vancouver, Canada. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

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

Development and commercialization of GMCSF-BclxL-derived chimeric therapeutics and immunotherapeutics, alone or in combination, for restoring, protecting, or stimulating cells in order to treat (i) cancer, (ii) neutropenia, (iii) CNS injury and (iv) Parkinson'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 December 27, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive patent license should be directed to: Surekha Vathyam, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4076; Facsimile: (301) 402–0220; Email: *vathyams@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The subject invention is to a chimeric protein comprising human granulocyte-macrophage colony stimulating factor (GMCSF) and B-cell lymphoma-extra large (BclxL). Chimeric proteins such as GMCSF-BclxL and its analogs have the potential to enhance cell survival, inhibit apoptosis and promote cell growth or proliferation (collectively referred to as ''anti-apoptotic''). Such anti-apoptotic proteins could have utility for restoring, protecting and stimulating cells in patients to treat a variety of disorders.

This technology relates to compositions comprising an anti-apoptotic chimeric protein and its use to inhibit apoptosis *in vivo* and *ex vivo.* One domain of the chimeric protein is the ligand for GMCSF receptor. Receptors for GMCSF are found on a

variety of normal tissues, including hematopoietic stem cells, neurons, and dendritic cells. The other domain is BclxL, which prevents targeted cell death. GMCSF-BclxL chimeric protein could potentially be used as an adjuvant to treat cancer and to treat acute neurological disorders (such as brain or spinal cord injury, stroke) or chronic CNS diseases (Alzheimers, Parkinson's, and ALS). It could be used to prevent hematopoietic cell loss during chemo or radiotherapy. It could also be used in patients receiving stem cell transplantation or in *ex vivo* expansion of hematopoietic stem and progenitor cells.

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 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.

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: November 21, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–28374 Filed 11–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: December 6, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Shiv A Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 21, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–28375 Filed 11–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4148–DR; Docket ID FEMA–2013–0001]

New Mexico; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Mexico (FEMA–4148–DR), dated September 30, 2013, and related determinations.

DATES: *Effective Date:* November 20, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Mexico is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of September 30, 2013.

Sierra County and the Navajo Nation for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–28473 Filed 11–26–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5683–N–103]

30-Day Notice of Proposed Information Collection: Assessment of Native American, Alaska Native and Native Hawaiian Housing Needs

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 27, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email