Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 29, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07903 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of 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: Council of Councils.

Open: May 14, 2013, 8:30 a.m. to 2:00 p.m.

Agenda: DPCPSI Update, Overview of Common Fund Epigenomics Program, Scientific Presentation, NIH Update, Concept Clearance and Discussion.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: May 14, 2013, 2:00 p.m. to 3:10 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: May 14, 2013, 3:10 p.m. to 5:00 p.m.

Agenda: Council Business Matters, Update on Implementation of NIH Policy on the Use of Chimpanzees in NIH-Supported Research, Update on Office of Disease Prevention.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robin Kawazoe, Executive Secretary, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 260, Bethesda, MD 20892, 301–402–9852.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/* where an agenda and proposals to be discussed will be posted before the meeting date.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April, 1, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07905 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of A Start-Up Commercialization Exclusive License: The Development of Fenoterol Analogues for the Treatment of Brain and Hepatocellular Cancers

AGENCY: National Institutes of Health, 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 Nova Therapeutics LLC of a start-up exclusive commercialization license to practice the inventions embodied in the following US Provisional Patent Application (and all domestic and foreign counterparts claiming priority to it): Serial No. 61/651,961, filed May 25, 2012, entitled, ''Methods of Regulating Cannabinoid Receptor Activity-related Disorders and Diseases'' [HHS Ref. E–139–2012/0–US–01]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective start-up exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

A worldwide exclusive license to the Patent Rights for research, development, manufacture, distribution, sale, and use in humans for the treatment of brain cancer or hepatocellular cancer within the Licensed Territory, exclusive of (*R,R'*)-4'-methoxy-1-napthylfenoterol (MNF), (*R,S'*)-4'-methoxy-1-napthylfenoterol, (*R,R'*)-ethylMNF, (*R,R'*)-napthylfenoterol, (*R,S'*)-napthylfenoterol, (*R,R'*)-ethyl-napthylfenoterol, and (*R,R'*)-4'-amino-1-napthylfenoterol, (*R,R'*)-4'-hydroxy-1-napthylfenoterol, (*R,R'*)-4-methoxy-ethylfenoterol, (*R,R'*)-methoxyfenoterol, (*R,R'*)-ethylfenoterol, and (*R,R'*)-fenoterol, and the respective stereoisomers of these compounds.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 22, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive commercialization 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 the discovery by the inventors that specific fenoterol analogues are cannabinoid receptor activators that can inhibit one or more signs or symptoms (such as growth) associated with a tumor that expresses a cannabinoid receptor. Using this discovery, the inventors developed the disclosed methods of treating a tumor expressing a cannabinoid receptor.

The prospective start-up exclusive commercialization 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 start-up 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.

Dated: April 1, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–07907 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Literature Review Approach ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid''; Request for Information and Comments

SUMMARY: The National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) in conjunction with the NIH Office of Dietary Supplements (ODS) is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature. The document is available on the NTP Folic Acid Request for Information (RFI) Web site (*http://ntp.niehs.nih.gov/go/38143*). Information gathered through this request will be used in prioritizing topics for the state of the science workshop.

DATES: The deadline for receipt of information and comments is May 28, 2013.

ADDRESSES: Comments should be submitted at *http://ntp.niehs.nih.gov/go/38143*.

FOR FURTHER INFORMATION CONTACT: Abee L. Boyles, Ph.D., Health Scientist, Office of Health Assessment and Translation, Division of the NTP, NIEHS, PO Box 12233, MD: K2–04, Research Triangle Park, NC 27709; telephone: (919) 541–7886; fax: (301) 480–3230; email: *abee.boyles@nih.gov*. Courier address: NIEHS, Room 2158, 530 Davis Drive, Morrisville, NC 27560 or Regan Bailey, Ph.D., R.D., Nutritional Epidemiologist, ODS, NIH, 6100 Executive Blvd., Room 3B01, Bethesda, MD 20892–7517; telephone: (301) 496–0187; fax: (301) 480–1845; email: *regan.bailey@nih.gov*.

SUPPLEMENTARY INFORMATION:

Background: The NTP in conjunction with the NIH ODS is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The benefit of supplemental folic acid for pregnant women to prevent neural tube defects in their children is well established; at the same time, there is interest in understanding potential adverse health impacts from high intakes of folic acid. This project aims to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid.

Due to the vastness of the research on folate and folic acid, screening of the literature was undertaken to identify the potential adverse health effects for which further research might be warranted. An approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' is available on the RFI Web site (*http://ntp.niehs.nih.gov/go/38143*) and should be referenced in responding to the RFI. This document (1) outlines the approach used to screen the literature, (2) describes the results of the screening effort, and (3) proposes a list of health outcomes for discussion at the workshop. As background for the workshop, a literature review document on these health outcomes will be prepared using systematic review methodology.

Humans require folate, a water-soluble B-complex vitamin, for the synthesis of nucleic acids and to provide methyl groups for biochemical reactions within cells. These functions are needed for everyday growth and cell division, including during critical periods of rapid growth and cell division such as embryonic development. Thus, folate is necessary for all individuals, but is especially important for women who may become pregnant. Evaluating the potential for adverse health effects associated with high folic acid intakes has been challenging because of the lack of systematic studies and other sources of evidence on this topic. In 1998, the Food and Nutrition Board of the Institute of Medicine set Dietary Reference Intakes that included the Recommended Dietary Allowances (RDAs) and tolerable upper intake levels (ULs)—the highest level of daily intake likely to pose no risk of adverse health effects to almost all of the population—for folic acid and other B vitamins. The folic acid UL (1000μg) was established with the paucity of data available to the committee at the time; i.e., limited but suggestive evidence that excessive folate intake may precipitate or exacerbate neuropathy in vitamin B12-deficient individuals. Since this 1998 publication that set the UL for folic acid, many publications have reported on health effects over a range of folic acid intakes. Some studies have raised concerns that high intake of folic acid may be associated with potential adverse health effects.

Folate is present in the diet through its natural occurrence in food, as a food additive, and as an ingredient in dietary supplements. Naturally occurring folate is unlikely to be associated with potential adverse effects because it has lower bioavailability than folic acid and its consumption is also limited by the bulk and caloric content of foods. Therefore, the primary substance of interest for considering the safety of high intake is folic acid, the form of folate commonly added to foods and dietary supplements.

Information gathered through this RFI will be used in prioritizing topics for the state of the science workshop. The date and location of the workshop have not yet been determined, but when set, will be announced in the **Federal Register**, the NIH Guide, and on the OHAT project Web site (*http://ntp.niehs.nih.gov/go/38144*). The overarching goals of this workshop are to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid. The workshop will bring together experts from multiple disciplines including, but not limited to, epidemiology, nutrition, medicine, and toxicology.

Request for Comments: The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature, which is available at *http://ntp.niehs.nih.gov/go/38143*. They also request information on issues related to evaluating potential adverse health effects of high intakes of folic acid. The RFI Web site contains specific questions for the following topics: