TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS—Continued

Pyrazinamide
Rolapitant hydrochloride
Triamcinolone acetonide (multiple reference listed drugs)
Umeclidinium bromide

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

Bacitracin
Buprenorphine
Clonidine
Cyclosporine
Dexlansoprazole
Diclofenac Epolamine
Erythromycin
Estradiol (multiple reference listed drugs)
Ethinyl Estradiol; Norelgestromin
Fentanyl
Granisetron
Icosapent ethyl
Lansoprazole
Lidocaine
Menthol; Methyl Salicylate
Mesalamine
Methylphenidate
Morphine sulfate
Nicotine
Nitroglycerin (multiple reference listed drugs)
Omega-3-acid ethyl esters
Oxybutynin
Oxycodone HCl
Pantoprazole sodium
Rivastigmine
Rotigotine
Scopolamine
Selegiline
Testosterone

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24050 Filed 10–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Kite Pharma, Inc. (''Kite'') located in Santa Monica, CA to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before October 20, 2016 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., 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: *andy.burke@nih.gov*

SUPPLEMENTARY INFORMATION: United States Provisional Patent Application No. 62/088,882, filed December 8, 2014, entitled ''Anti-CD70 Chimeric Antigen Receptors'' [HHS Reference No. E–021–2015/0–US–01]; and PCT Application No. PCT/US2015/025047 filed April 9, 2015 entitled ''Anti-CD70 Chimeric Antigen Receptors'' [HHS Reference No. E–021–2015/0–PCT–02] (and U.S. and foreign patent applications claiming priority to the aforementioned applications).

The patent rights in these inventions have been assigned 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 the development, manufacture and commercialization of retrovirally-engineered anti-CD70 chimeric antigen receptor (CAR)-based autologous peripheral blood T cell therapy products, as set forth in the Licensed Patent Rights, for the treatment of CD70 expressing cancers in humans.

The present invention describes certain CARs targeting CD70. CARs are hybrid proteins comprised of extracellular antigen binding domains and intracellular signaling domains designed to activate the cytotoxic functions of CAR-transduced T cells upon antigen stimulation.

CD70 is a co-stimulatory molecule that provides proliferative and survival cues to competent cells upon binding to its cognate receptor, CD27. Its expression is primarily restricted to activated lymphoid cells; however, recent research has demonstrated that several cancers, including renal cell carcinoma, glioblastoma, non-Hodgkin's lymphoma, and chronic myelogenous leukemia also express CD70 under certain circumstances. Due to its limited expression in normal tissues, CARs targeting CD70 may be useful in adoptive cell therapy protocols for the treatment of select cancers.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent 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: September 29, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center. National Cancer Institute.

[FR Doc. 2016–24030 Filed 10–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Consortium for Food Allergy Research: Leadership Center (UM2).

Date: November 16–18, 2016.

Time: 7:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Andrea L. Wurster, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G33B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20899823, (240) 669–5062, *wurstera@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 29, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24026 Filed 10–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: November 9, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 6710 B, Rm 2133, Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Bethesda Drive, Bethesda, MD 20892, 301–435–6916, *kielbj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 29, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24027 Filed 10–4–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Cooperative Study Group for Autoimmune Disease Prevention (CSGADP).

Date: November 3–4, 2016.

Time: Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 4H100, 5601 Fishers Lane, Rockville, MD 20892.

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activates, Room 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–507–9685, *thomas.conway@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 29, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–24025 Filed 10–4–16; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–