Radiological Health's (CDRH) Patient Engagement Advisory Committee (the PEAC or Committee). The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, particularly encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received by November 21, 2016, will be given first consideration for membership on the Committee. Nominations received after November 21, 2016, will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* please select Academician/Practitioner in the drop down menu, to apply for membership, or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX: 301–847–8640. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5441, 301–796–8398, FAX: 301–847–8510, *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for the Committee. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

I. General Description of the Committee's Duties

The PEAC provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes and increase integration of patient perspectives into the regulatory process for medical devices.

The PEAC provides advice on issues relating to medical devices, the regulation of devices, and their use by patients. A variety of topics may be considered by the PEAC, including Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs or designee from candidates who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research participants. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area.

Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from Industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted.

Nominations should include a cover letter; a current, complete resume or curriculum vitae for each nominee, including a current business and/or home address, telephone number, and email address if available; and should specify the advisory committee for which the nominee is recommended.

Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–24100 Filed 10–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on June 17, 2016 (81 FR 39672). This notice announces draft product-specific BE recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

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

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

Acetaminophen; Oxycodone hydrochloride
Alectinib hydrochloride
Betamethasone dipropionate
Betamethasone valerate
Captopril
Carbidopa; levodopa
Cholic acid
Clobetasol propionate (multiple reference listed drugs)
Cobicistat; Elvitegravir; Emtricitabine; Tenofovir alafenamide fumarate
Crotamiton (multiple reference listed drugs)
Desonide
Dexlansoprazole
Elbasvir; grazoprevir
Eltrombopag Olamine
Esomeprazole magnesium
Fluticasone propionate
Halobetasol propionate
Hydrocodone bitartrate (multiple reference listed drugs)
Hydrocortisone valerate
Ibuprofen
Iron dextran
Methylphenidate hydrochloride
Morphine sulfate
Olopatadine hydrochloride
Oxymorphone hydrochloride
Prochlorperazine

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.