requesting that the Agency determine whether PFIZERPEN (penicillin G potassium) Injection, 1 units/vial, and penicillin G potassium injection, 1 million units/vial, had been withdrawn from sale for reasons of safety or effectiveness. Penicillin G potassium Injection, 1 million units/vial, is the subject of ANDA 65–079, held by Sandoz, and approved on August 30, 2002.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness (this determination also applies to penicillin G potassium injection, 1 million units/vial, ANDA 65–079). The petitioner believes that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn for reasons of safety or effectiveness because it was discontinued due to commercial reasons. We have carefully reviewed our files for records concerning the withdrawal of PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29034 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Budesonide Extended-Release Tablets; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Budesonide Extended-Release Tablets.'' The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for budesonide extended-release tablets.

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 comments 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 February 9, 2015.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1615, Silver Spring, MD 20993–0002, 240–402–7290.

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,'' which 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 to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for budesonide extended-release tablets.

New drug application 203634 for UCERIS (budesonide) extended-release tablets, 9 milligrams (mg), was initially approved by FDA in January 2013. FDA is now issuing a draft guidance for industry on BE recommendations for generic budesonide extended-release tablets.

In February 2013, Santarus, Inc., submitted a citizen petition requesting that FDA: (1) Issue an individual BE guidance for budesonide extended-release tablets and (2) refrain from approving any ANDA that identifies UCERIS (budesonide) extended-release tablets as the reference listed drug unless the generic product is shown to be bioequivalent based on appropriate data from a clinical efficacy endpoint study, comparative pharmacokinetic testing, in vitro dissolution testing, and pharmacoscintigraphy studies (Docket No. FDA 2013–P–0127). FDA reviewed the issues raised in the petition and is responding to the petition today in a letter that will be included in the citizen petition docket.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for budesonide extended-release tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the

heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29035 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-Up Exclusive Patent License Agreement: Use of Compounds Covered by Patent Rights for Diagnosis of Human Thyroid Cancer Requiring FDA Premarket Approval or an Equivalent Authority Outside of the United States, and Treatment of Human Thyroid Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License to Nova Therapeutics LLC, a company having a place of business in Delaware, to practice the inventions embodied in the following patent applications:

(a) PCT Patent Application No. PCT/US2008/11958, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–PCT–01

(b) Australian Patent No. 2008–363295, Filed: October 20, 2008, HHS Ref No.: E–284–2008/0–AU–02

(c) Canadian Patent Application No. 2,741,030, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–CA–03

(d) European Patent Application No. 08876356.0, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–EP–04

(e) Indian Patent Application No. 3684/DELNP/2011, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–IN–05

(f) Japanese Patent Application No. 2011–532048, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–JP–06

(g) U.S. Patent No. 8,741,259 U.S. Patent Application No. 13/125,045, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–US–07

(h) U.S. Patent Application No. 13/897,330, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–US–08 Current status: pending

(i) U.S. Patent Application No. 14/243,821, Filed: October 20, 2008, HHS Ref. No.: E–284–2008/0–US–10

The patent rights in this invention have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide and the field of use may be limited to: Use of compounds covered by Patent Rights for diagnosis of human thyroid cancer requiring FDA premarket approval or an equivalent authority outside of the United States, and treatment of human thyroid cancer.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before December 26, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License Agreement should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4074; Facsimile: (301) 402–0220; Email: *Lauren.Nguyen-antczak@nih.gov.* A signed confidentiality nondisclosure agreement will be required to receive copies of any patent application(s) that have not been published or issued by the United States Patent and Trademark Office of the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This invention concerns small molecule compounds that agonize the activity of the thyroid stimulating hormone receptor (''TSHR''). These TSHR agonists enhance or activate the thyroid stimulating hormone (''TSH'') signaling pathway by directly binding to the transmembrane domain of TSHR. Invention compounds may be administered alone or in combination with radioactive iodine to detect thyroid cancer cells. Additionally, invention compounds may be administered in combination with radioactive iodine to treat thyroid cancer, such as to ablate thyroid remnants in patients after a thyroidectomy.

The prospective Start-Up Exclusive Patent License that is being considered can be found at *http://www.ott.nih.gov/forms-model-agreements#SUMLA,* which complies with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Patent License is being provided under the small business initiative launched on 1 October 2011. The prospective Start-Up Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, 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 filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up 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: December 4, 2014.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–29017 Filed 12–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings 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.

The meetings 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