Our estimate is based on our experience with the submission of labeling materials for human prescription drugs. Because this is a new collection of information, we are specifically interested in receiving comments from respondents to the information collection regarding our burden estimate.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06565 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–3883]

Determination That CORTISPORIN (Hydrocortisone/Neomycin Sulfate/Polymyxin B Sulfate) Otic Solution, 10 Milligrams/Milliliter Hydrocortisone, 3.5 Milligrams Base/Milliliter Neomycin Sulfate, 10,000 Units/Milliliter Polymyxin B Sulfate, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 milligrams (mg)/milliliter (mL) hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, is the subject of NDA 050479, held by Monarch Pharmaceuticals LLC, and initially approved on December 9, 1975. CORTISPORIN is indicated for the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Foley & Lardner LLP submitted a citizen petition dated October 11, 2018 (Docket No. FDA–2018–P–3883), under § 10.30 (21 CFR 10.30), requesting that the Agency determine whether CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was withdrawn from sale for reasons of safety or effectiveness.

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 CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CORTISPORIN (hydrocortisone/neomycin sulfate/polymyxin B sulfate) otic solution, 10 mg/mL hydrocortisone, 3.5 mg base/mL neomycin sulfate, 10,000 units/mL polymyxin B sulfate, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06549 Filed 4–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Frederick National Laboratory Advisory Committee to the National Cancer Institute was renewed for an additional two-year period on March 30, 2019.

It is determined that the Frederick National Laboratory Advisory Committee to the National Cancer Institute is in the public interest in connection with the performance of duties imposed on the National Cancer Institute and National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Acting Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *harriscl@nih.gov*.

Dated: April 1, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–06569 Filed 4–3–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-Like tyrosine kinase 3 (FLT3) Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive/Co-Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Senti Bio (''Senti''), located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before April 19, 2019 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive/Co-Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer 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)–276–7856; Facsimile: (240)–276–5504; Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–133–2016: FLT3-Specific Chimeric Antigen Receptors and Methods Using Same

1. US Provisional Patent Application 62/342,394, filed May 27, 2016 (E–133–2016–0–US–01);
2. International Patent Application PCT/US2017/034,691, filed May 26, 2017 (E–133–2016–0–PCT–02)
3. EP Patent Application No.:17729627.4, filed December 11, 2018 (E–133–2016/0–EP–03)
4. US Patent Application No.: 16/304,552, filed November 26, 2018 (E–133–2016/0–US–05
5. Australia Patent Application No.: 2017271606, filed November 13, 2018 (E–133–2016/0–AU–06)
6. Canadian Patent Application No.: 3025516, filed November 23, 2018 (E–133–2016/0–CA–07)
7. Japan Patent Application No.: 2018–561669, filed November 22, 2018 (E–133–2016/0–JP–08)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive/co-exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to: ''the development of a universal/split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, for the prophylaxis or treatment of cancers expressing FMS-like tyrosine kinase 3 (FLT3; also known as CD135), wherein the CAR construct binds to the FLT3-binding domain referenced as NC7 in the invention, but NC7 is not included in the CAR construct. Specifically excluded from the field of use for this exclusive license are FLT3-specific CAR -based immunotherapies wherein the CAR construct comprises the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain.'' The proposed territory is worldwide.

A co-exclusive license to: ''the development of a multi-specific FLT3 CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.'' The proposed territory is worldwide.

A co-exclusive license to: ''the development of a FLT3-specific Regulated/Switch/Logic-Gated CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.'' The proposed territory is worldwide.

This technology discloses a CAR therapy that targets FLT3 by utilizing the anti-FLT3 binder known as NC7. FLT3 (CD135) is a cytokine receptor expressed on hematopoietic progenitor cells and is one of the most frequently mutated genes in acute myeloid leukemia (AML) and infant acute lymphoblastic leukemia (ALL). FLT3 mutation leads to increased cell surface expression and therefore on leukemic cells, which makes it an attractive candidate for cellular therapies such as CAR–T.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive/co-exclusive license will be royalty bearing, and the prospective exclusive/co-exclusive license 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