Dated: February 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04361 Filed 3–2–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3082]

Determination That NEO TECT KIT (Kit for the Preparation of Technetium TC–99m Depreotide Injection) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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or Agency) has determined that NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to the product, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Michelle T. Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0374, *Michelle.Weiner@fda.hhs.gov.*

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 approved previously. 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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 it 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.

NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is the subject of NDA 021012, currently held by CIS Bio International SA, approved on August 3, 1999. NEO TECT KIT is a scintigraphic imaging agent that identifies somatostatin receptor-bearing pulmonary masses in patients presenting with pulmonary lesions on computed tomography and/or chest x ray who have known malignancy or who are highly suspect for malignancy.

NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is listed as Discontinued in the Orange Book.

Andarix Pharmaceuticals, Inc. submitted a citizen petition dated June 25, 2019 (Docket No. FDA–2019–P–3082), under 21 CFR 10.30, requesting that the Agency determine whether NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was withdrawn from sale voluntarily for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records with respect to NEO TECT KIT and based on the information we have at this time, FDA has determined under § 314.161 that NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was not withdrawn from sale for reasons of safety or effectiveness. FDA carefully reviewed its files for records concerning the withdrawal of NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) from sale. In addition, the Agency independently evaluated relevant literature and data for possible post-marketing 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 NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) 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 NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) 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: February 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04319 Filed 3–2–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–2615 and FDA–2018–E–2616]

Determination of Regulatory Review Period for Purposes of Patent Extension; ILUMYA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ILUMYA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by May 4, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for