4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-1516]

Determination That SODIUM PERTECHNETATE TC-99M (Technetium Tc-99m Sodium Pertechnetate) Injection, Oral, 2 to 100 Millicuries per Milliliter and 10 to 60 Millicuries per Milliliter, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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) has determined that SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 millicuries per milliliter (mCi/mL) and 10 to 60 mCi/mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for technetium Tc-99m sodium pertechnetate, injection, oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6228, Silver Spring, MD 20993-0002, 240-402-4191.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL, is the subject of NDA 17-471, held by GE Healthcare. SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 10 to 60 mCi/mL, is the subject of NDA 17-725, held by Mallinckrodt Pharmaceuticals. The most recent labeling indicates that SODIUM PERTECHNETATE TC-99M is used in adults as an agent for thyroid imaging, salivary gland imaging, urinary bladder imaging (direct isotopic cystography) for the detection of vesicoureteral reflux, and nasolacrimal drainage system imaging (dacryoscintigraphy). The most recent labeling also indicates that SODIUM

PERTECHNETATE TC-99M is used in children as an agent for thyroid imaging and urinary bladder imaging (direct isotopic cystography) for the detection of vesicoureteral reflux.

In a letter dated April 15, 2004, Amersham Health, the former holder of NDA 17-471, notified FDA that SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the Federal Register of March 4, 2005 (70 FR 10651), FDA announced that it was withdrawing approval of NDA 17-471. In a letter dated October 23, 2006, Mallinckrodt Pharmaceuticals, the holder of NDA 17-725, notified FDA that SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 10 to 60 mCi/mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the Federal Register of November 7, 2007 (72 FR 62858), FDA announced that it was withdrawing approval of NDA 17-725.

Spectron mrc, LLC, submitted a citizen petition dated November 19, 2013 (Docket No. FDA-2013-P-1516), under 21 CFR 10.30, requesting that the Agency determine whether SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, were 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 SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SODIUM

PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10-60 mCi/mL, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, 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 these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, 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 SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, 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: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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