DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

June 2, 2014

David Trump, Ph.D.
Spectron mrc, LLC
17490 Dugdale Drive
South Bend, IN 46635

Re: Docket No. FDA-2013-P-1516

Dear Dr. Trump:

This letter responds to your citizen petition dated November 19, 2013, and received November 21, 2013, requesting that the Food and Drug Administration (FDA) determine whether SODIUM PERTECHNETATE TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 millicuries/milliliter (mCi/mL) and 10 to 60 mCi/mL, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined 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TC-99M (technetium Tc-99m sodium pertechnetate) Injection, Oral, 2 to 100 mCi/mL and 10 to 60 mCi/mL, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain 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 *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please contact me at 240-402-4191.

Sincerely,

Ayako Sato
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

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Pertechnetate) Injection, Oral, 2 to 100 Millicuries per Milliliter and 10 to 60 Millicuries per Milliliter, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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sodium pertechnetate) Injection, Oral, 2 to 100 millicuries per milliliter (mCi/mL) and 10 to 60 mCi/mL, were not withdrawn from sale for reasons of safety or effectiveness.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.

[FR Doc. 2014–12351 Filed 5–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0622]

Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs; 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 "Best Practices in Developing Proprietary Names for Drugs." The draft guidance focuses on the safety aspects in the development and selection of proposed proprietary names for all prescription and nonprescription human drug products and biological products. The draft guidance describes naming design practices to help avoid medication errors and provides a qualitative systematic framework for evaluating proprietary names before submitting them for FDA review. FDA is issuing this draft guidance to help drug and biologic product sponsors develop proprietary names that do not cause or contribute to medication errors or otherwise contribute to the misbranding of the drug.

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 July 28, 2014.

ADDRESSES: Submit written requests for single copies of this 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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: Kellie Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–0157, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs." FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors, and has addressed this issue repeatedly in recent decades. Our primary focus has been to develop and communicate to sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product review and approval process. As part of this initiative, FDA held public meetings in June and December 2003 to discuss the methods used for proprietary name evaluation. In 2007, FDA formally committed to certain performance goals (under the reauthorization of the Prescription Drug User Fee Act (PDUFA IV) (Public Law 110–85), including implementing measures to reduce medication errors related to look-alike and sound-alike proprietary names (PDUFA IV performance goals). In 2008, FDA held a public meeting to further discuss testing and evaluating proprietary names, and initiating a pilot project on proprietary name review. The 2008 meeting focused on advances and current limitations in the science of proprietary name evaluation, FDA's recommendations for best practices in the absence of a "gold standard," and details of the proposed pilot project. The participating expert panel judged all the evaluation methods proposed by FDA to be complementary and of value in the proprietary name testing process. We are issuing this guidance in partial fulfillment of the PDUFA IV performance goals.

This draft guidance document, which addresses minimizing risks through the design of drug product naming, is the last in a series of three guidance documents that FDA is issuing to help sponsors minimize the potential for medication errors when designing and developing products. The first draft guidance, published in the **Federal Register** on December 13, 2012 (77 FR 74196), focuses on minimizing risks associated with the design of the drug product and its container closure system. The second draft guidance, published in the **Federal Register** on April 24, 2013 (78 FR 24211), focuses on safety aspects of the container label and carton labeling design.

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 best practices for developing and selecting proposed proprietary names to minimize medication errors. 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Proprietary name information submitted under 21 CFR part 314 has been approved under OMB control number 0910–0001, and proprietary name information submitted under 21 CFR part 601 has been