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2013 NOV 21 A 11:20

November 19, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to issue a notice that Sodium Pertechnetate Tc-99m (technetium Tc-99m sodium pertechnetate) was not withdrawn from sale for reasons of safety or effectiveness.

I. Action Requested

The undersigned requests that the following summary statement (with revisions as needed) be issued: "The Food and Drug Administration (FDA) has determined that Sodium Pertechnetate Tc-99m (technetium Tc-99m sodium pertechnetate) injection, oral, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Sodium Pertechnetate Tc-99m injection, oral, if all other legal and regulatory requirements are met."

The undersigned also requests that the following statement (with revisions as needed) be issued: "FDA has reviewed its records and, under § 314.161, has determined that Sodium Pertechnetate Tc-99m (technetium Tc-99m sodium pertechnetate) injection, oral, was not withdrawn from sale for reasons of safety or effectiveness.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, 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, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA

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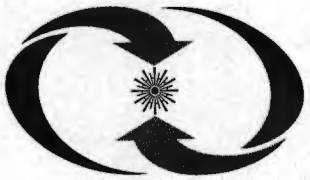

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determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling."

II. Statement of Grounds

Reprinted from the notice by FDA titled "Determination That SODIUM FLUORIDE F 18 (Sodium Fluoride F-18) Injection, 10 to 200 Millicuries per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness" (FR Doc. 2011-15815, filed 6-23-11): "In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (98) (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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 (§ 314.162 (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 (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), is the subject of NDA 17-471 (Applicant: GE Healthcare) and NDA 17-725 (Applicant: Mallinkrodt). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn (see FR Doc. E7-21886 filed 11-6-07 and FR Doc. 05-4158 Filed 3-3-05).

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Spectron mrc, LLC is making progress toward production of ^{99m}Tc-sodium pertechnetate using a cyclotron for the purposes of alleviating the current shortfall in our region caused by lower output from nuclear reactors world-wide, and to aid the White House efforts to minimize the use of highly enriched uranium (see the White House press release, June 07, 2012).

III. Environmental Impact

The actions requested in this petition will have no significant effect on the human environment.

IV. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

David Trump, Ph.D.
Spectron mrc, LLC
17490 Dugdale Drive
South Bend, IN 46635
574-271-2800

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