June 25, 2019

Andarix Pharmaceuticals, Inc.
141 Powderhouse Blvd,
Somerville, MA 02144

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

CITIZEN PETITION

Greetings,

The undersigned submits this petition under 21 C.F.R.§§ 10.25(a), 10.30, and 314.161(a)(3) to request the Commissioner of Food and Drugs to make a determination as to whether a listed drug that has been voluntarily withdrawn from sale in the United States was withdrawn for safety or effectiveness reasons.

A. Action Requested

According to publicly-available reports (see Orange Book Listing in Appendix 1), Cis Bio International, SA voluntarily withdrew its drug, Neo Tect Kit (Kit for the preparation of Technetium Tc 99m Depreotide Injection NDA 021012) from commercial distribution. The undersigned is seeking a determination by the Commissioner that the Cis Bio International, SA's voluntary withdrawal of Neo Tect Kit from sale was for reasons other than safety or effectiveness.

Andarix Pharmaceuticals, Inc. respectfully requests that, if the commissioner confirms our conclusion, the agency annotate the listing for Neo Tect Kit in the Orange Book to indicate that it was not withdrawn for reasons of safety and effectiveness. If instead, the commissioner determines that Neo Tect Kit was withdrawn from distribution for safety and effectiveness reasons, we request that the agency publish a notice of this determination in the Federal Register. The petitioner respectfully requests that the Commissioner take the requested action as soon as possible.

B. Statement of Grounds

On August 8, 1999, the FDA approved NDA 021012 for Neo Tect Kit. A full and complete copy of the summary basis of approval for this application is provided in Appendix 2. According to the approved prescribing information included in this document, Neo Tect Kit was originally manufactured and distributed by Diatide, Inc. (Londonderry, New Hampshire). The Neo Tect Kit was then transferred to Cis Bio International, SA.

Neo Tect Kit (Kit for the preparation of Technetium Tc 99m depreotide Injection, NDA 021012) continues to be listed as a Discontinued product in the electronic Orange Book on FDA's web site as previously shown in Appendix 1. However, it does not have any annotation such as "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons", next to it.

Information from the Neo Tect Kit summary basis of approval NDA file obtained from FDA website does not include any implication that the product was discontinued for reasons of safety and effectiveness. The initial prescribing information (approved in 1999) provided that Neo Tect Kit was indicated as 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. There were neither contraindications nor warnings listed in the package insert. Headache was the most commonly reported adverse event.

In addition, an extensive review of the literature regarding commercially available Technetium Tc 99m depreotide preparations did not identify any publications or safety advisories suggesting safety or efficacy concerns for Neo Tect Kit. Andarix Pharmaceuticals, Inc. therefore found no evidence of safety or efficacy concerns with regards to this agent.

C. Environmental Impact Statement

A claim for categorical exclusion from the requirement of submission of an environmental assessment is made pursuant to 21 C.F.R. § 25.31, on the basis that the use of the active moiety would not be increased.

D. Economic Impact

Information on the economic impact of this request will be provided on request.

E. 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

Sincerely,

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