FDA U.S. FOOD & DRUG ADMINISTRATION

DEC 23 2019

Christopher P. Adams
Chief Executive Officer
Andarix Pharmaceuticals, Inc.
141 Powderhouse Blvd.
Somerville, MA 02144

Re: Docket No. FDA-2019-P-3082

Dear Mr. Adams:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition, submitted on behalf of Andarix Pharmaceuticals, Inc., received on June 26, 2019. Your petition requests that the Agency determine whether NEO TECT KIT (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) was withdrawn from sale voluntarily for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 C.F.R. §10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research