



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 26, 2019

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

Sent via email to: cadams@andarix.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA make a determination as to whether a listed drug that has been voluntarily withdrawn from sale in the United States was withdrawn for safety or effectiveness reasons was received by this office on 06/26/2019.

It was assigned docket number FDA-2019-P-3082. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)