



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

July 3, 2019

Sharif Ahmed
Principal Consultant
Lachman Consultants
1600 Stewart Ave, Suite 604
Westbury, NY 11590

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determine whether the Reference Listed Drug (RLD), NIX (Permethrin) Topical Lotion, NDA 019435 held by GLAXO SMITHKLINE (GSK), has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons was received by this office on 07/02/2019.

It was assigned docket number FDA-2019-P-3232. 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)