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

September 22, 2022

Re: Docket No. FDA-2019-P-3232

Dear Mr. Ahmed:

This letter responds to your citizen petition dated July 2, 2019, requesting that the Food and Drug Administration (FDA) determine whether Nix (permethrin) 1% topical creme rinse, new drug application (NDA) 019435 held by GlaxoSmithKline, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Nix (permethrin) 1% topical creme rinse (NDA 019435) was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Nix (permethrin) 1% topical creme rinse (NDA 019435) in the Discontinued Drug Product List section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

However, Nix (permethrin) 1% topical creme rinse, which was originally approved for prescription use under NDA 019435, was subsequently approved under a separate NDA (NDA 019918) for nonprescription use. According to section 503(b)(4)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug not required to be dispensed with a prescription under section 503(b)(1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the "Rx only" symbol. Because FDA concluded that there is no meaningful difference between the currently marketed nonprescription Nix product and its previous prescription version, Nix and any generic product referencing prescription Nix (NDA 019435) would be misbranded under section 503(b)(4)(B) of the FD&C Act if its label were to bear the "Rx only" symbol. Moreover, FDA will not approve ANDAs that refer to prescription Nix (NDA 019435).

Enclosed is a copy of the *Federal Register* notice that announces and explains the FDA determination. If you require any further information, please feel free to call me at (301) 796-3977.

Sincerely,

Linda Jong -S Digitally signed by Linda Jong -S
Date: 2022.09.22 08:58:29 -04'00'

Linda Jong
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure