U.S. FOOD & DRUG ADMINISTRATION

DEC 18 2019

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

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

Dear Sir/Madam:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on July 2, 2019. Your petition requests that the Agency determine whether NIX (permethrin) Topical Lotion, new drug application 019435 held by Glaxo SmithKline, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

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 CFR 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 Bennett

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