July 02, 2019

Division of Dockets Management
Food and Drug Administration (HF A-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client, pursuant to Federal Food, Drug, and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration 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Listed Drug (RLD), NIX (Permethrin) Topical Lotion, NDA 019435 held by GLAXO SMITHKLINE (GSK), has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products. These drug products are generally eligible for submission under Section 505(j) of the FD&C Act as ANDAs. Like 505(j) applications, a 505(b)(2) applicant also relies on the Agency's finding of safety and effectiveness for an approved drug to the extent such reliance would be permitted under the generic drug approval provisions at section 505(j).

NIX (Permethrin) Topical Lotion, NDA 019435 held by GLAXO SMITHKLINE (GSK), was approved on March 31, 1986. The product was then considered to be a "listed drug product" in the Orange Book. NIX (Permethrin) Topical Lotion (NDA 019435) now appears in the "Discontinued Section" of the Orange Book (refer to Attachment A), indicating that it is currently not available for sale.

If an RLD appears in the Discontinued Section of the Orange Book and the FDA has not

determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, an applicant must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a). If the FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from the Orange Book. *See* 21 C.F.R. § 314.122, § 314.161, and § 314.162.

Petitioner is further unaware of any reason why NIX (Permethrin) Topical Lotion (NDA 019435) may have been removed from sale and believes the discontinuation of NIX (Permethrin) Topical Lotion, NDA 019435 was due to commercial considerations. Petitioner requests that FDA determine whether the NDA holder for NIX (Permethrin) Topical Lotion (NDA 019435) has withdrawn the product for reason of safety or effectiveness.

C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.3l (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Sharif Ahmed

Digitally signed by Sharif Ahmed
Date: 2019.07.02 17:05:22 -04'00'

Sharif Ahmed
Principal Consultant