MEDEXUS PHARMA

June 9, 2022

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

Dear Sir / 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Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.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), ARISTOSPAN® (triamcinolone hexacetonide injectable suspension, USP), 20 mg/mL, NDA 016466 held by Sandoz Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

Under the FD&C Act, an Abbreviated New Drug Application (ANDA) must rely on FDA's approval findings for a Reference Listed Drug (RLD). See FD&C Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug product, must petition FDA for a determination of whether the drug product was withdrawn for reasons of safety or effectiveness per 21 C.F.R. §314.122 and §314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book per 21 C.F.R. § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

In addition, according to 21 C.F.R § 314.122(a), "An abbreviated new drug application that refers to, or a petition under section 505(j)(2)(c) of the act and § 314.93 that relies on, a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons." Therefore, a Citizen Petition is required to ensure that FDA determines whether the RLD was discontinued for safety or efficacy reasons prior to

approval of the submitted ANDA.

The RLD ARISTOSPAN® (triamcinolone hexacetonide injectable suspension, USP), 20 mg/mL, NDA 016466 held by Sandoz Inc., was approved on 29 July 1969, has not been available for sale commercially since 2016.

Petitioner is further unaware of any reason why ARISTOSPAN® (triamcinolone hexacetonide injectable suspension, USP), 20 mg/mL (NDA 016466) may have been removed from sale and believes the discontinuation of ARISTOSPAN® (triamcinolone hexacetonide injectable suspension, USP), 20 mg/mL (NDA 016466) was due to commercial considerations. Petitioner requests that FDA determine whether the NDA holder for ARISTOSPAN® (triamcinolone hexacetonide injectable suspension, USP), 20 mg/mL, (NDA 016466) 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

Pursuant to 21 C.F.R. § 10.30(b), Petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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,

Khaled M Mohamed
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