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August 19, 2022

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

The undersigned submits this petition under 21 C.F.R. §§ 10.25 and 10.30, and Section 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request the Commissioner of Food and Drugs determine whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. ACTIONS REQUESTED

Petitioner requests that the Commissioner promptly determine whether Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, approved under New Drug Application ("NDA") number 008816, held by Akorn Operating Co. LLC, has been voluntarily withdrawn or discontinued from sale for reasons of safety or effectiveness. The undersign requests FDA declare that is appropriate to submit an Abbreviated New Drug Application ("ANDA") for Xylocaine® (Lidocaine Hydrochloride) Jelly 2% that relies on an RLD that is no longer marketed.

B. STATEMENT OF GROUNDS

Under FDA regulations, drugs are withdrawn from market if FDA withdraws or suspends approval of the drug application for reasons of safety and effectiveness, or if FDA determines that the drug was withdrawn or withheld from sale for reasons of safety or effectiveness. *See* 21 C.F.R. § 314.162. The regulations also provide that FDA must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety and effectiveness before an ANDA that refers to that listed drugs may be approved. *See* 21 C.F.R, § 314.161(a)(1). If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a Reference Listed Drug ("RLD").

Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, was approved by FDA under NDA No. 008816 prior to January 1, 1982 and is currently held by Akorn Operating Co LLC ("Akorn") as detailed in the Orange Book listing. Akorn's Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, was also listed as a RLD in the Orange Book.

The current listing of Akorn's Xylocaine® (Lidocaine Hydrochloride) Jelly 2% product in the electronic Orange Book accessed August 17, 2022 shows the product listed as "Discontinued" (refer to the attached screen shot from the Orange Book in **Attachment 1**). It is noted that there are three ANDAs for Lidocaine Hydrochloride Jelly, 2% listed as RX in the Orange Book with Lidocaine Hydrochloride Jelly ANDA 040433 listed as the Reference Standard. To the best of the Petitioner's knowledge, the discontinuation of the drug product was not made for safety and effectiveness reasons but rather for sales and marketing reasons.

As stated above, at the time of submission of this Petition, there is no evidence that Akorn's Xylocaine® (Lidocaine Hydrochloride) Jelly 2% has been discontinued from marketing for safety or efficacy reasons. Therefore, it is requested that FDA determine whether Akorn's decision to discontinue marketing its Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, approved under NDA No. 008816 was for reasons of safety and effectiveness.

C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT

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 that are unfavorable to the Petition.

Respectfully submitted,

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Attachment 1: Electronic Edition of the Orange Book showing the discontinued status of Xylocaine® (lidocaine hydrochloride) Jelly 2%