HIBROW HEALTHCARE LLC

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MINNETONKA, MINNESOTA 55305
UNITED STATES OF AMERICA

September 23, 2019

Electronic Submission

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

CITIZEN PETITION

Dear Sir/Madam,

The undersigned submits this petition pursuant to 21 C.F.R § 10.30 and in accordance with regulation 21 C.F.R § 314.161

A. Action Requested

The petitioner requests that the Commisioner of the Food and Drug Administration (FDA) determine that Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL were not voluntarily withdrawn for safety and efficacy reasons.

B. Statement of Grounds

1. The above reference drug products were approved under ANDA 071609 of Teva Pharmaceuticals USA on November 09, 1987, the product is the reference standard as per current Electronic Orange Book. This product was initially approved against the Reference Listed Drug (RLD) Doxepin Hydrochloride (Sinequan) NDA N017516 of Pfizer Laboratories Div Pfizer INC which was discontinued from marketing, FDA have determined that this product was not discontinued or withdrawn for safety or efficacy reasons.

2. The above mentioned reference standard was not available in the market, even the label is not available in the Dailymed website. Since the product is not available in the market either it might be short of supply or it might be discontinued.

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3. An abbreviated new drug application (ANDA) seeking approval of a generic formulation of limited or no quantities of the reference standard in distribution, or discontinued reference standard must be accompanied by a Citizen Petition. If FDA's determination that the reference standard was not voluntarily withdrawn for safety or effectiveness reasons than a new reference standard to be assigned. Kindly refer the following guidance and regulations "Referencing Approved Drug Products in ANDA Submissions Guidance for Industry, 21 C.F.R § 314.122 and 21 C.F.R § 314.161".

4. At the time of submission there is no evidence that the applicant of the reference standard is currently marketing its Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL.

5. Because these products have been discontinued from marketing, it is requested that the FDA determine whether the applicant holder's decision to discontinue marketing, as approved under ANDA 071609, was for reason for safety or effectiveness.

6. From current electronic orange book two generic drug products were approved and marketed for Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL. ANDA 074721 and ANDA 071918 of Lannett co Inc and Wockhardt Bio AG respectively.

7. We request Food and Drug Administration to assign new Reference Standard status to either ANDA 074721 or ANDA 071918, for Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL for referencing in potential ANDA submission.

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this petition.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this Citizen Petition includes all information and views upon which the petition relies,

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and includes representative data and information known to the petitioner which are unfavourable to the petition.

Sincerely,

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