PHARMOBEDIENT

February 21, 2024

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

Dear Sir/Madam,

The undersigned submits this Citizen Petition in accordance with Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §10.25(a), §10.30, §314.122 and 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether the listed drug product was withdrawn for safety or effectiveness reasons.

A. Action Requested

The Petitioner, Pharmobedient requests that the Commissioner of the Food and Drug Administration (FDA) determine whether the Reference Listed Drug (RLD) TAVIST (Clemastine Fumarate) Tablets, 2.68 mg under New Drug Application (NDA) 017661 held by NOVARTIS was voluntarily withdrawn from commercial distribution or withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The FDA maintains a list of drug products, in the *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly referred to as the "Orange Book". The Orange Book includes information regarding a drug's designation as either a Reference Listed Drug (RLD) or Reference Standard (RS). Drugs designated as RLD may be referenced as the basis of submission for Abbreviated New Drug Applications (ANDAs) under Section 505(j) of the FD&C Act. TAVIST (Clemastine Fumarate) Tablets, 2.68 mg, NDA 017661, was approved prior to Jan 1, 1982 and was listed as the RLD against which generic equivalents could be developed and approved in an ANDA. The Orange Book currently identifies TAVIST (Clemastine Fumarate) Tablets, 2.68 mg in the "Discontinued Drug Product List" section of the Orange Book. RS listed is #A073283 of Teva and marketed in 2.68 mg strength in the Orange Book.

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If an RLD appears in the Discontinued Section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a Citizen Petition under 21 CFR §10.25(a) and §10.30 before or at the same time as the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 CFR § 314.122(a)

The regulations provide that the FDA must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or efficacy before an ANDA that refers to that listed drug may be approved (21 CFR § 314.161(a)(1)).

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 CFR §314.122, §314.161 and § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety or efficacy, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.

The electronic version of the Orange Book currently identifies the marketing status of TAVIST (Clemastine Fumarate) Tablets, 2.68 mg, as discontinued. The Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of TAVIST (Clemastine Fumarate) Tablets, 2.68 mg under NDA 017661 was only due to commercial considerations.

Accordingly, the Petitioner respectfully requests the FDA to confirm that TAVIST (Clemastine Fumarate) Tablets, 2.68 mg was not withdrawn from sale for safety or efficacy reasons.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR §25.31(a) and §25.40, the Petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

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D. Economic Impact

In accordance with 21 CFR § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the Petition. Petitioner hereby commits to promptly provide this information, if so requested.

E. Certification

The undersigned certifies to the best of its knowledge and belief, 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,

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