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September 13, 2022

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

Hyman, Phelps & McNamara, P.C. submits this Petition in accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 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and 314.161 to request that the Food and Drug Administration ("FDA") promptly determine whether a listed drug was withdrawn for safety or effectiveness reasons.

A. ACTIONS REQUESTED

Petitioner requests that FDA determine whether Hydrochlorothiazide Oral Solution, 50 mg/5mL, approved under Abbreviated New Drug Application ("ANDA") number 088587, held by Roxane Laboratories, Inc., has been voluntarily withdrawn for reasons of safety or effectiveness.

B. STATEMENT OF GROUNDS

Under the FDC Act, an ANDA must rely on FDA's approval findings for a Reference Listed Drug ("RLD"), *see* FDC Act § 505(j)(2), which may include a listed drug identified by FDA as a Pre-Hatch-Waxman ANDA ("PANDA"), *see* FDA, Notice, 86 Fed. Reg. 44,731, 44,734 (Aug. 13, 2021) ("After consideration of the history of PANDAs, FDA determined that it was appropriate and consistent with FDA's general practice regarding the designation of RLDs to designate PANDA products as RLDs because these products were approved for safety and effectiveness under section 505(c) of the FD&C Act."). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. *See* 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 If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing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. *See id.* § 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 If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies Hydrochlorothiazide Oral Solution, 50 mg/5mL, approved on July 2, 1984 under ANDA 088587—a PANDA—in the "Discontinued Drug Product List" section of the Orange Book. FDA appears to have moved ANDA 088587 to the "Discontinued Drug Product List" in the March 2009 Cumulative Supplement to the 29th edition of the Orange Book. The approval of ANDA 088587 was withdrawn effective August 20, 2010. *See* FDA, Notice, Novartis Pharmaceuticals Corp. et al.; Withdrawal of Approval of 27 New Drug Applications and 58 Abbreviated New Drug Applications, 75 Fed. Reg. 42,455, 42,458 (July 21, 2010), *available at* https://www.govinfo.gov/content/pkg/FR-2010-07-21/pdf/2010-17785.pdf.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of Hydrochlorothiazide Oral Solution, 50 mg/5mL, under ANDA 088587 was due only to commercial considerations.

Petitioner requests that FDA determine that Hydrochlorothiazide Oral Solution, 50 mg/5mL, approved under ANDA 088587, was not withdrawn for reasons of safety or effectiveness.

C. ENVIRONMENTAL IMPACT

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

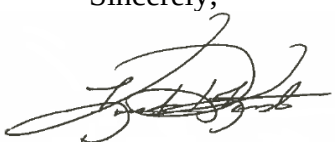
D. ECONOMIC IMPACT STATEMENT

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.

Sincerely,



Kurt R. Karst

KRK/dlw