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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§§ 314.122 and 314.161 to request that the Food and Drug Administration (“FDA”) determine whether a listed drug was withdrawn for safety or effectiveness reasons.

A. ACTIONS REQUESTED

Petitioner requests that FDA determine whether Lithium Citrate Oral Syrup, 300 mg Carbonate/5 mL, approved under New Drug Application (“NDA”) number 018421, held by Hikma Pharmaceuticals, USA Inc., has been voluntarily withdrawn for reasons of safety or effectiveness.¹

B. STATEMENT OF GROUNDS

Under the FDC Act, an Abbreviated New Drug Application (“ANDA”) must rely on FDA’s approval findings for a Reference Listed Drug (“RLD”). *See* FDC 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a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.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 If FDA determines that the listed drug was withdrawn from sale for reasons of safety and

¹ Petitioner notes that on November 2, 2022, Saptalis Pharmaceuticals LLC also requested that FDA make a determination as to the withdrawal of Lithium Citrate Oral Syrup, 300 mg Carbonate/5 mL, approved under NDA 018421. *See* FDA-2022-P-2752, available at <https://www.regulations.gov/document/FDA-2022-P-2752-0001>.

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 If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.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 Lithium Citrate Oral Syrup, 300 mg Carbonate/5 mL, approved on December 23, 1980 under NDA 018421, in the “Discontinued Drug Product List” section of the Orange Book. FDA appears to have moved NDA 018421 to the “Discontinued Drug Product List” in the April 2022 Cumulative Supplement to the Orange Book.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of Lithium Citrate Oral Syrup, 300 mg Carbonate/5 mL, under NDA 018421 was due only to commercial considerations.

Petitioner requests that FDA determine that Lithium Citrate Oral Syrup, 300 mg Carbonate/5 mL, approved under NDA 018421, 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,

A handwritten signature in black ink, appearing to read 'Kurt R. Karst', with a stylized flourish at the end.

Kurt R. Karst