November 2, 2022

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

(The Reference Listed Drug Product is not available and the approved product is on FDA Drug Shortage List)

Dear Sir/Madam,

The undersigned, for Saptalis Pharmaceuticals LLC (Saptalis), a specialty pharmaceutical company focusing on developing and marketing of generic and branded drugs, submits this petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with regulations under 21 C.F.R. §10.25(a) and §10.30, and 21 C.F.R. §314.161, requesting the Commissioner of Food and Drug Administration (FDA) to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. ACTION REQUESTED

The petitioner requests that the Commissioner of FDA determine whether the Reference Listed Drug (RLD), Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL, New Drug Application (NDA) Number N018421, held by Hikma Pharmaceuticals, USA Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or effectiveness.

B. STATEMENT OF GROUNDS

The list of all FDA approved products, known as "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" is maintained by the Food and Drug Administration. These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs.

The Orange Book lists drug product, Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL, New Drug Application (NDA) Number N018421 held by Hikma Pharmaceuticals, USA Inc, was Approved prior to January 1, 1982. The product is considered as a "Reference Listed Drug Product" in the Orange Book.

At present, the RLD, Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL (NDA# N018421) appears in the "Discontinued Section" of the Orange Book (Refer to Attachment I), indicating that it is currently not available for sale.

If an RLD appears in the discontinued section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, a person wishing to submit an ANDA for the drug must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before or at the same time of the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons.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 C.F.R. § 314.122(a).

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

If the FDA determines that the listed drug was withdrawn from sale for reasons of safety or 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. Refer to 21 C.F.R. § 314.122, § 314.161, and § 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 an RLD.

Petitioner is further unaware of any reason why Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL (NDA# N018421) may have been removed from sale and believes the discontinuation of Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL was only due to commercial considerations. Petitioner requests that FDA determine whether the NDA holder for Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL (NDA# N018421) has withdrawn the product for reasons of safety or effectiveness.

At present the drug product, Lithium Citrate Syrup EQ 300 mg Carbonate/5 mL is listed on "FDA Drug Shortages" since May 6, 2020 (Refer to Attachment II). In order to provide product to needy patients and to meet the market requirement, as a drug manufacturer, Saptalis Pharmaceuticals,

LLC developed the generic equivalent drug product Lithium Oral Solution, USP (Potency: Lithium Ion 8 mEq/5 mL) and subsequently submitted the ANDA #217183 to the agency for approval. The prompt action shall facilitate Saptalis generic product approval by FDA which will have greater beneficial impact to the patients and Healthcare system affected by shortage of the product.

Therefore, Saptalis Pharmaceuticals, LLC, requests that Agency promptly determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness to expedite the approval of our submitted ANDA #217183 for Lithium Oral Solution, USP (Potency: Lithium Ion 8 mEq/5 mL).

C. ENVIRONMENTAL IMPACT

In accordance with the requirements set forth in 21 C.F.R. §25.31(a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. ECONOMIC IMPACT

In accordance with the requirements set forth in 21 C.F.R. §10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

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 which is unfavorable to the petition.

For correspondence, please contact Saptalis Pharmaceuticals, LLC, Regulatory Affairs Office by email at rekha.kallam@saptalis.com or by phone at (631) 231-2751 Ext. 106.

Sincerely,

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Product Details for NDA 018421

LITHIUM CITRATE (LITHIUM CITRATE)
EQ 300MG CARBONATE/5ML
Marketing Status: Discontinued

Active Ingredient: LITHIUM CITRATE
Proprietary Name: LITHIUM CITRATE
Dosage Form; Route of Administration: SYRUP; ORAL
Strength: EQ 300MG CARBONATE/5ML
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N018421
Product Number: 001
Approval Date: Approved Prior to Jan 1, 1982
Applicant Holder Full Name: HIKMA PHARMACEUTICALS USA INC
Marketing Status: Discontinued
Patent and Exclusivity Information (patent_info.cfm?Product_No=001&Appl_No=018421&Appl_type=N)

Drug Databases (https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases)

FDA Drug Shortages

Current and Resolved Drug Shortages and Discontinuations Reported to FDA

Report a Drug Shortage (https://www.fda.gov/drugs/drug-shortages/how-report-shortage-or-supply-issue) | Contact Us (/scripts/email/cder/drugshortages.cfm) | FAQ (dsp_faq.cfm) | Background Info (https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages) | (https://service.govdelivery.com/service/subscribe.html?code=USFDA_22)Get Email Alerts (https://updates.fda.gov/subscriptionmanagement) | Download Current Drug Shortages (Drugshortages.cfm)

Search by Generic Name or Active Ingredient: Enter at least three characters Submit

Start Over (default.cfm) | Back to Previous Screen (default.cfm#tabs-1)

Lithium Oral Solution
Status: Currently in Shortage
»Date first posted: 05/06/2020
»Therapeutic Categories: Psychiatry

Hikma Pharmaceuticals USA, Inc. (formerly West-Ward) (*Reverified 10/06/2022*)

Company Contact Information:
800-631-2174 **(mailto:)** **(mailto:)**

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
8 mEq/5 mL 500 mL bottle (NDC 0054-3527-63)	Unavailable, Estimated Shortage: TBD		Shortage of an active ingredient