November 3, 2022

Rekha Kallam
Saptalis Pharmaceuticals, LLC
45 Davids Drive
Hauppauge, NY 11788

Sent via email to: rekha.kallam@saptalis.com

Dear Petitioner:

Your submission requesting that the 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mL, New Drug Application (NDA) Number N018421, held by Hikma Pharmaceuticals, USA Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 11/02/2022.

It was assigned docket number FDA-2022-P-2752. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.11.03 09:42:03 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)