DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17812 S-031
NDA 18421 S-031
NDA 18558 S-026

**SUPPLEMENT APPROVAL**

West-Ward Pharmaceuticals International Limited
C/O Hikma Pharmaceuticals US
Attention: Jerald Andry, PharmD, MS
Senior Director, Drug Regulatory Affairs and Medical Affairs
1809 Wilson Road
Columbus, OH 43228

Dear Dr. Andry:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 14, 2018 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lithium Carbonate Capsules 150mg, 300mg, 600mg (NDA 17812), Lithium Carbonate Tablets 300mg (NDA 18558), and Lithium Oral Solution 8meq/5ml (NDA 18421).

This "Changes Being Effected" supplemental new drug application was submitted in response to our August 22, 2018 CBE supplement request letter and provides for the addition of pediatric use information to the Indications and Usage, Dosage and Administration, Adverse Reactions, Use in Specific Populations, Clinical Pharmacology, and Clinical Studies sections of labeling, along with updates to the Medication Guide.

## APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Keith Kiedrow, PharmD, MS, RAC, Team Leader, Senior Regulatory Project Manager, at 301-796-1924

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Prescribing Information
Medication Guide

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/
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MITCHELL V Mathis
10/04/2018