DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-027 / S-055

JDS Pharmaceuticals, LLC
Attention: Salvatore J. Pinella
405 Lexington Avenue
59th Floor
New York, NY 10174

Dear Mr. Pinella:

Please refer to your supplemental new drug application dated and received April 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lithobid (lithium carbonate, USP) Extended-Release Tablets, 300mg.

We acknowledge receipt of your submission dated June 22, 2006.

This "Changes Being Effected" supplemental new drug application changes the nomenclature from Slow-Release to Extended-Release as requested in the Division's letter of October 7, 2002. In addition, the **INDICATIONS** section of the labeling was updated to match the language in lithium carbonate regular release tablets as follows:

> **INDICATIONS**
> LITHOBID® (lithium carbonate) is indicated in the treatment of manic episodes of Bipolar Disorder. Bipolar Disorder, Manic (DSM-IV) is equivalent to Manic Depressive illness, Manic, in the older DSM-II terminology. LITHOBID® is also indicated as a maintenance treatment for individuals with a diagnosis of Bipolar Disorder. Maintenance therapy reduces the frequency of manic episodes and diminishes the intensity of those episodes which may occur.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 22, 2006 (attached).

If you have any questions, call Doris Bates, Ph.D., Senior Regulatory Project Manager, at (301) 796-1040.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research