DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-027/S-051

JDS Pharmaceuticals LLC
Attention: Mr. Michael Satow
112 East 42nd Street
New York, NY 10168

Dear Mr. Satow:

Please refer to your supplemental new drug application dated February 4, 2005, received February 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lithobid (Lithium Carbonate, USP) Slow-Release Tablets, 300 mg.

We also reference your NDA Annual Report Y-030, submitted and received July 15, 2005.

This "Changes Being Effected" supplemental NDA provides for:

a) a change in the manufacturer's name on the container labeling and the package insert for this product to accurately reflect Solvay Pharmaceuticals, Inc., as the product manufacturer for JDS Pharmaceuticals LLC.
b) a change in the tablet imprinting from "Solvay 4492" to "Lithobid 300"
c) a change in the NDC code for the product from 0032-4492-01 to 68968-4492-01.

We note that a typographical error in the package insert was corrected after the supplement was submitted. The NDC number was also revised to change the terminal digits from -01 to -1.

The version of labeling [package insert] which includes the correction has been submitted in your Annual Report Y-030, referenced above, which also includes a copy of the immediate container labeling [bottles of 100] showing the revised NDC number terminating in -1.

We have completed our review of this application, including the corrected package insert and revised bottle label which are provided in the referenced Annual Report. This application is approved, effective on the date of this letter, based on the final printed container labeling [bottles of 100 tablets] and package insert with corrections and revisions as presented in Y-030.

However, we note that the change in tablet imprint affects the tablet specification with regard to the description of the tablet. Evaluation of tablet appearance is part of the approved stability testing program for the drug product, and therefore we request that you submit a revised specification for the tablets reflecting this change in their appearance. This should be submitted in your next NDA Annual Report.

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, contact Doris J. Bates, Ph.D., Regulatory Project Manager, at (301).796.1040.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Food and Drug Administration

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
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