DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 18-027/S-040, S-046, S-049

Solvay Pharmaceuticals, Inc.
Attention: Judy Tian, Manager
CNS Product Liaison
901 Sawyer Road
Marietta, GA 30062

Dear Ms. Tian:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lithobid Slow Release Tablets, 300 mg.

18-027/SLR-040
dated: September 16, 1994
amended: September 23, 1994

The supplemental application provides for changes to labeling due to acquisition of the NDA by Solvay Pharmaceuticals from Ciba-Geigy Corporation. The supplement consolidates the labeling for the following lithium products: LithoTabs & Cibolith-S Syrup, LithoBID, Lithonate Syrup & Capsules. We also note that the LithoTabs, Cibolith-S Syrup, and Lithonate Syrup & Capsule NDAs have been subsequently withdrawn from the market.

18-027/SLR-046
dated: August 27, 1998

The supplement provides proposed labeling changes in compliance with the Agency's August 27, 1997 Final Rule (Federal Register Vol. 62, pages 45313-45326) regarding information pertinent to the appropriate use of drugs in the elderly.

18-027/SLR-049
dated: April 3, 2002
amended: August 9, 2002

The supplement provides revised labeling to include text regarding the potential for a pharmacokinetic interaction between cyclooxygenase-2 inhibitors (COX-2) and lithium. This change was made in response to an Agency letter dated February 4, 2002.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the attached draft labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

The attached labeling utilizes version 8E Rev 5/2002 as the base label and the changes proposed in your prior approval supplement SLR-046 have been incorporated utilizing an underline/strikeout method for clarity.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* (January, 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submission should be designated "FPL for approved supplement NDAs 18-047/S-040 & S-046." Approval of these submissions by FDA is not required before the labeling is used.

Supercede

We have reviewed the content of the following labeling supplements and note that the changes provided for have either been superceded by later supplemental applications or have been incorporated into the enclosed labeling text. Therefore, these supplemental applications have been superceded and will be retained in our files with no further action. Please note that these supplemental applications were submitted by the previous sponsor of the application, the Ciba-Geigy Corporation.

	Dated:	Amended:
18-027/SLR-025	June 13, 1986	July 21, 1987
18-027/SLR-027	January 12, 1987	February 2, 1989
18-027/SLR-035	August 31, 1989	July 23, 1991

Additional Request

Finally, please note that the Agency presently utilizes the following nomenclature for extended-release products. We ask that you revise your labeling, including carton/container labeling, as follows.

Current Name:	Proposed Name:
Lithobid®	Lithobid®
(Lithium Carbonate, USP)	(Lithium Carbonate extended-release tablets)
Slow-Release Tablets 300 mg	Tablets 300 mg

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Doris Bates, Ph.D., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment

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

/s/

Russell Katz

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