DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-189/S-018

Wallace Pharmaceuticals
A Division of MedPointe Healthcare, Inc.
Attention: Ms. Maureen Garner
Director, Regulatory Affairs
P.O. Box 1001/Half Acre Road
Cranbury, NJ 08512-0181

Dear Ms. Garner:

Please refer to your supplemental new drug application dated November 13 2000, received November 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Felbatol (felbamate) Tablets and Felbatol (felbamate) Oral Suspension.

We also refer to your submission dated May 21, 2002.

This "Changes Being Effected" supplemental new drug application provides for revisions to language in the package insert pertaining to hepatotoxins. These changes were made in accordance with Division guidance provided in a letter dated May 23, 2000.

We have completed the review of this supplemental application, as amended, 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 agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 21, 2002).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-189/S-018." Approval of this submission by FDA is not required before the labeling is used.

Supercede

We have reviewed the content of the following labeling supplements, and note that these changes have been incorporated into the submitted draft labeling (package insert submitted May 21, 2002). Therefore, the supplemental applications listed below have been superceded, and will be retained in our files with no further action.

Application:	Provides for:
NDA 20-189/S-013 NDA 20-189/S-017	Additions to the **Postmarketing Adverse Events** subsection of the package insert to include adverse events that have been reported during postmarketing experience with Felbatol®.
NDA 20-189/S-015	Revisions to the **Drug Interactions** subsection of the package insert to include statements about interactions of felbamate with phenobarbital and low-dose combination oral contraceptives.
NDA 20-189/S-016	Revisions to the **Pharmacokinetics** subsection and the PRECAUTIONS and DOSAGE AND ADMINISTRATION sections to include information from a study of Felbatol in otherwise-healthy, renally-impaired subjects. In addition, the storage temperature statement was revised to the ICH range of 20-25 C, and the prescription drug legend was deleted.

Request for Information

We note that, in the above supplement (S-017), you updated the **Postmarketing Adverse Event Reports** subsection to the **ADVERSE REACTIONS** section to include the phrase "…, leukemia, including myelogenous leukemia, and lymphoma, including T-cell and B-cell lymphoproliferative disorders" under the Hematologic category. At this time, we ask that you review your NDA safety database and your postmarketing safety database for all cases of lymphoma and leukemia and submit a report of your findings to us.

MedWatch

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Other

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 Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-5533.

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

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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