NDA 16-033/S-011

GlaxoSmithKline
Attention: Willa Phyall
Associate Director
U.S. Regulatory Affairs
One Franklin Plaza
200 N 16th Street
Philadelphia, PA 19102

06 AUG 2001

Dear Ms. Phyall:

Please refer to your supplemental new drug application dated April 11, 1990, received April 17, 1990, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vontrol Tablets.

This "Changes Being Effected" supplemental new drug application provides for the revisions to the Dosage and Administration, "Children –For Nausea and Vomiting" section as follows:

- The sentence "Unit doses in children are best calculated by body weight: usually 0.4mg/lb" has been deleted from the first paragraph.
- In the second paragraph, the word "dose" has been replaced with "dosage".
- In the note, the word "dosage" has been replaced with "dose".

We have completed the review of this supplemental application 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 April 10, 1990.

Please submit the copies of final printed labeling (FPL) electronically to each application 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 submissions should be designated "FPL for approved supplement NDA 16-033/S-011". Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Please submit one market package of the drug product when it is available.

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, please call Melaine Shin, R.Ph., Regulatory Management Officer, at (301) 594-5793.

Sincerely,

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