



NDA 10-571 / S-096

GlaxoSmithKline
Attention: Philip A. Witman
Manager, US Regulatory Affairs
P.O. Box 61540
King of Prussia, PA 19406-2772

Dear Mr. Witman:

Please refer to your supplemental new drug application dated May 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Compazine (prochlorperazine) Tablets.

Your submission of August 18, 2004, constituted a complete response to our action letter of April 12, 2004.

This supplemental new drug application provides for the addition of a "Geriatric Use" subsection in the labeling.

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 April 12, 2004 (attached).

We note that marketing of Compazine Tablets was discontinued in the US effective November 2003.

If you have any questions, call CAPT Steven D. Hardeman, R.Ph., Acting Chief, Project Management Staff, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

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

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/s/

Thomas Laughren
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