DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12-429/S-017

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Matthew Whitman
Manager, Regulatory Affairs

Dear Mr. Whitman:

Please refer to your supplemental new drug application dated July 10, 2001, received July 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tabloid (thioguanine) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the package insert to add a warning concerning the risk of rapid bone marrow depression after thioguanine treatment in patients with a thiopurine methyltransferase enzyme (TMPT) deficiency. A statement has also been added to warn that this problem may be exacerbated by the coadministration of drugs that inhibit TPMT, such as olsalazine, mesalazine, or sulphalazine. The Drug Interactions section of the PRECAUTIONS section has been updated with information concerning drugs that may inhibit the TPMT enzyme.

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 submitted final printed labeling (package insert RL911 dated May 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

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

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

If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology 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/

Richard Pazdur

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