DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-429 / S-021

SmithKlineBeecham Corporation d/b/a GlaxoSmithKline
2301 Renaissance Blvd.
Bldg. 510 (RN0210)
P.O. Box 61540
King of Prussia, PA 19406-2772

Attention: Matthew Whitman
Associate Director, U.S. Regulatory Affairs

Dear: Mr. Whitman:

Please refer to your supplemental new drug application dated November 5, 2003 submitted under section 505(b) pursuant to section 505(b)2 of the Federal Food, Drug, and Cosmetic Act for Tabloid (thioguanine) 40 mg Tablets.

This supplemental new drug application provides an update to the WARNINGS, PRECAUTIONS: Laboratory Tests, and DOSAGE and ADMINISTRATION sections to include a sentence that laboratory tests are available to measure TPMT deficiency in patients and substantial dosage reductions may be indicated.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the November 5, 2003 agreed upon labeling text, with revisions to shorten the references.

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

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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 individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 12-429 / S-019." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: labeling

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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