DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 09-053 / S-022

SmithKlineBeecham Corporation d/b/a GlaxoSmithKline
1250 S. Collegeville Road
P.O. Box 5089
Philadelphia, PA 19426-0989

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

Dear: Mr. Whitman:

Please refer to your supplemental new drug application dated November 25, 2002, received November 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Purinethol (mercaptopurine) Tablets.

This "Changes Being Effected" supplemental new drug application provides for updated safety information in the package insert. The insert has been revised under **CONTRAINDICATIONS**, **WARNINGS, PRECAUTIONS, OVERDOSAGE,** and **DOSAGE AND ADMINISTRATION** in accordance with our March 22, 2002 approval letter for S-020.

Additionally, this supplemental new drug application provides updated safety information in the package insert. The insert has been revised under **ADVERSE REACTIONS**(to add reports of alopecia and oligospermia), **OVERDOSAGE** [Active measures (such as the use of activated charcoal or gastric lavage) may not be effective in the event of overdose unless the procedure can be undertaken within 60minutes of ingestion] and **DOSAGE AND ADMINISTRATION** (Studies in pediatric patients with acute lymphoblastic leukemia suggest that the administration of PURINETHOL in the evening compared with the morning lowered the risk of relapse) as requested in our September 6, 2002 approval letter for S-021.

We have completed our review of this supplemental new drug application and it is approved as of the date of this letter.

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 the requirements for an approved NDA set forth under 21 CFR 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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