DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-669 / S-029

SmithKline Beecham d/b/a GlaxoSmithKline
2301 Renaissance Blvd., Bldg. 510
P.O. Box 61540
King of Prussia, PA 19406-2772

Attention: Richard Swenson, Ph.D.
Director, Regulatory Affairs

Dear Dr. Swenson:

Please refer to your supplemental new drug application dated November 29, 2004, received December 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leukeran® (chlorambucil) Tablets.

This supplemental new drug application provides for addition of the following statement:

> **PRECAUTIONS-General:** Administration of live vaccines to immunocompromised patients should be avoided.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed upon November 29, 2004 labeling.

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 Sheila Ryan, Pharm.D., Regulatory Project Manager, at (301) 594-5771.

Sincerely,

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/

Robert Justice
5/24/05 05:29:46 PM