



NDA 20-207 / S-012

SmithKlineBeecham 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 14, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alkeran (melphalan hydrochloride) for Injection.

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 labeling submitted November 29, 2004.

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).

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If you have any questions, call Sheila Ryan, Pharm.D., 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
6/14/05 10:00:22 AM