



NDA 14-691/S-023
NDA 20-207/S-005

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

Attn: Matthew Whitman
Manager, U.S. Regulatory Affairs

Dear Mr. Whitman:

Please refer to your supplemental new drug applications dated November 16, 2001, received November 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alkeran (mephalan) Tablets 2 mg, and Alkeran (mephalan hydrochloride) for Injection.

These "Changes Being Effected" supplemental new drug applications provide for updated safety information under the ADVERSE REACTIONS: Gastrointestinal subsection to include specific information concerning hepatic disorders. The section now reads as follows:

Gastrointestinal disturbances such as nausea and vomiting, diarrhea, and oral ulceration occur frequently. Hepatic disorders ranging from abnormal liver function tests to clinical manifestations such as hepatitis and jaundice have been reported.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the November 16, 2001 final printed labeling. Accordingly, these supplemental applications are 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

NDA 14-691/S-023
NDA 20-207/S-005
Page 2

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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