



NDA 09-386 / S-023

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 September 25, 2003 submitted under section 505(b) pursuant to section 505(b)2 of the Federal Food, Drug, and Cosmetic Act for Myleran (busulfan) Tablets.

This supplemental new drug application provides for the addition of a Geriatric Use Subsection in the labeling.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

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 09-386 / S-021.” 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  
12/24/03 09:13:44 AM