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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

9-386/S-019

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 09-386/S-019

SmithKlineBeecham d/b/a GlaxoSmithKline
P.O. Box13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Attention: Kevin A. Miller, R.Ph., RAC
Associate Director, CMC Regulatory Affairs

Dear Mr. Miller:

Please refer to your supplemental new drug application dated July 16, 2002, received July 17, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Myleran (busulfan) Tablets.

Your July 16, 2002 submission constituted a complete response to our April 1, 2002 action letter. Additionally, we acknowledge your January 16, 2003 submission containing revised labeling.

This supplemental new drug application provides for the manufacture of a reformulated Myleran (busulfan) Tablets 2 mg in a High Containment Facility (HCF) at Glaxo Wellcome Operations in Dartford, UK.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the January 16, 2003 agreed upon labeling text. The final labeling (FPL) must be identical to the enclosed labeling.

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-019. Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Maureen A. Pelosi, Regulatory 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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