CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

14-691/S-020

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 14-691 S-020

GlaxoSmithKline
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709

Attention: Kevin C. Fitzgerald, R.Ph.
Senior Assistant Director, Technical Regulatory Affairs

Dear Mr. Fitzgerald:

We acknowledge receipt of your June 6, 2001 submission containing final printed labeling in response to our May 24, 2001 letter approving your supplemental new drug application for ALKERAN (melphalan) Tablets 2 mg..

We have reviewed the labeling that you submitted in accordance with our May 24, 2001 letter and we find it acceptable.

If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

/S/

{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/

Dotti Pease
6/25/01 07:20:52 AM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 14-691/S-020

GlaxoWellcome
Five Moore Drive
PO Box 13398
Research Triangle, NC 27709-3398

Attention: Kevin C. Fitzgerald, R.Ph.
Senior Assistant Director

Dear Mr. Fitzgerald:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Alkeran® (melphalan) Tablets

NDA Number: 14-691

Supplement Number: S-020

Date of Supplement: December 6, 2000

Date of Receipt: December 7, 2000

This supplement proposes the following change(s): To seek approval to manufacture reformulated Alkeran® (melphalan) Tablets 2mg in your Facility at Glaxo Wellcome Operations in Dartford, UK.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 5, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be April 7, 2001 and the secondary user fee goal date will be June 5, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products,
HFD-150
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products,
HFD-150
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

/S/

Dotti Pease
Chief, Project Management Staff
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

/s/

Dotti Pease
1/9/01 02:00:53 PM