DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-388/S-010

SmithKlineBeecham dba GlaxoSmithKline
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Attention: Ann-Margaret Martin
Director, Regulatory Affairs, Oncology

Dear Ms. Martin:

Please refer to your supplemental new drug application dated September 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Navelbine (vinorelbine tartrate) Injection.

We acknowledge receipt of your submission dated September 11, 2001. Your submission of September 11, 2001 constituted a complete response to our August 17, 2001 approvable letter.

This supplemental new drug application provides for revised labeling text based on the results of a Phase 4 study conducted by the Southwest Oncology Group (SWOG 9308).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 20-388/S-010." Approval of this submission by FDA is not required before the labeling is used.

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

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

Enclosure