DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Michele Hardy
Director, Advertising Policy
GlaxoSmithKline Inc.
Five Moore Drive
Research Triangle Park, NC 27709

RE: NDA # 20-388
Navelbine® (vinorelbine tartrate) Injection
MACMIS # 10153

Dear Ms. Hardy:

This letter notifies GlaxoSmithKline Inc. (GSK) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified promotional activities that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, GSK made a false or misleading claim regarding the safety of Navelbine in the commercial exhibit hall of the 37th American Society of Clinical Oncology (ASCO) Annual Meeting held in San Francisco, California in May 2001.

Misleading Risk Presentation

In the commercial exhibit booth, GlaxoSmithKline's representative claimed that compared to platin-based regimens, "patients using Navelbine don't feel like they received chemotherapy." This claim is misleading because it is not supported by substantial evidence and is not consistent with the approved product labeling (PI). The PI contains a boxed warning that states "Severe granulocytopenia resulting in increased susceptibility to infection may occur." Furthermore, the PI indicates that side effects such as asthenia, injection site reactions, nausea, vomiting, constipation, peripheral neuropathy and alopecia occur frequently with the use of Navelbine.

Promotional statements or materials are false, lacking in fair balance, or otherwise misleading when they contain representations or suggestions that a drug is safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence. GSK's claim is a violation of the Act because it misleadingly suggests that Navelbine has less serious side effects than has been demonstrated.

Requested Actions

GSK should immediately cease making the claim described above and other promotional activities or materials for Navelbine that make the same or similar claims or presentations. GSK should submit a written response to DDMAC on or before July 13, 2001, describing its

intent and plans to comply with the above. In its letter to DDMAC, GSK should include the date on which this and other similarly violative materials were discontinued.

GSK should direct its response to me by facsimile at (301) 594-6771 or by written communication at the Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 10153 in addition to the NDA number. DDMAC reminds GSK that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joseph A. Grillo, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joseph Grillo
6/28/01 12:55:49 PM