DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JUN 21 1999

Michele M. Hardy
Director, Advertising and Labeling Policy
Regulatory Affairs
Glaxo Wellcome, Inc.
Five Moore Drive
Research Triangle Park, NC 27709

RE: NDA 20-388
Navelbine (vinorelbine) for Injection
MACMIS ID# 7826

Dear Ms. Hardy:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional advertising material for Navelbine (vinorelbine) disseminated by Glaxo Wellcome (GW) that violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Reference is made to a journal ad (NAV359RO), submitted under cover of Form FDA 2253 on March 25, 1999. DDMAC has reviewed this material and has determined that it is lacking in fair balance, or otherwise misleading. DDMAC requests that the use of the above referenced material and those containing similar claims or presentations cease immediately.

RISK INFORMATION

In this advertisement, GW makes several claims of effectiveness, yet provides inadequate balancing risk information. Promotional materials should present true information relating to side effects and contraindications that is comparable in scope, depth, and detail with the claims for effectiveness or safety. In this advertisement, the only statements devoted to risk information are: "*Contraindicated in patients with pretreatment granulocyte counts <1,000 cells/mm^3*" and "*In North American clinical trials, mild to moderate peripheral neuropathy occurred in 20% of NSCLC patients.*" Thus, the limited risk information in this journal ad does not effectively balance the claims for efficacy or safety.

The approved product labeling for Navelbine is replete with important warnings

(including a boxed warning), precautions, and severe adverse reactions associated with the use of the drug, including, but not limited to:

- Patients treated with Navelbine should be frequently monitored for myelosuppression both during and after therapy.
- Severe granulocytopenia resulting in increased susceptibility to infection may occur.
- Granulocytopenia is dose-limiting.
- Other severe adverse events such as dyspnea and liver dysfunction.
- Other common adverse events such as nausea, vomiting, diarrhea, and anorexia.

Therefore, to present fair balance between risks and benefits of the drug, the most important of these warnings, precautions, and adverse reactions should be included in promotional materials for Navelbine.

GW should immediately cease using the referenced material and all other promotional materials containing the same or similar claims and presentations. GW should submit a written response to DDMAC, on or before July 5, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, GW should include a list of all promotional materials that were discontinued, and the discontinuation date.

If you have any questions, please contact the undersigned by telephone at (301) 827-2831, facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds GW that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7826 and NDA 20-388.

Sincerely,

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications