



TRANSMITTED VIA FACSIMILE

Michele Hardy
Director, Advertising and Labeling Policy
Regulatory Affairs
GlaxoWellcome
Five Moore Drive
Research Triangle Park, NC 27709

MAR 09 1999

RE: **NDA 20-007**
Zofran® (ondansetron hydrochloride) injection
MACMIS # 7671

Dear Ms. Hardy:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Zofran® (ondansetron hydrochloride) injection disseminated by GlaxoWellcome Inc. (GlaxoWellcome) that violate the Federal Food Drug and Cosmetic Act and its implementing regulations. Reference is made to the following promotional material submitted under cover of form FDA 2253: Pen (ZO2732R0). DDMAC has reviewed this material and has determined that it promotes Zofran in a manner that is false or misleading because it lacks fair balance.

The above material is promotional labeling. The above piece includes the following promotional statements relating to the effectiveness of Zofran; "Zofran Can," "24-hour control," "Prevention of Emesis 1 to 2 days After Chemotherapy," "Radiation -induced Emesis," "Pediatric," "Emetogenic Chemotherapy," "Post-operative Nausea and Vomiting." However, the piece fails to present any information regarding the risks associated with the drug. Promotional materials must present information relating to the side effects and contraindications of the drug with a prominence and readability reasonably comparable to the presentation of effectiveness of the drug. Therefore, this material would be considered false or misleading because it lacks fair balance.

GlaxoWellcome should immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information. GlaxoWellcome should submit a written response to DDMAC on or before March 19, 1999, describing its intent and plans to comply with the above.

GlaxoWellcome should direct its response to the undersigned by facsimile at (301) 594-6771,

Michele Hardy
GlaxoWellcome Inc.
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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 GlaxoWellcome that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7671 and NDA 20-007.

Sincerely

/S/

John C. Markow R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications