DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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TRANSMITTED VIA FACSIMILE

FEB 16 1999

Timothy Urschel
Assistant Director, Regulatory Affairs
Anthra Pharmaceuticals
103 Carnegie Center, Suite 102
Princeton, NJ 08540

RE: NDA 20-892
Valstar (valrubicin)
MACMIS ID#7589

Dear Mr. Urschel:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional labeling materials for Valstar (valrubicin) disseminated by Anthra Pharmaceuticals that violate the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Reference is made to a NSS Stuffer and NSS Fax Blast #1, submitted under cover of Form FDA 2253 on February 1, 1999. DDMAC has reviewed these materials and has determined that they are misleading and lacking in fair balance. DDMAC requests that the use of the above referenced materials and those containing similar promotional claims or presentations cease immediately.

MISLEADING INDICATION STATEMENT

DDMAC considers the NSS Fax Blast #1 to be product-specific labeling material because it suggests that Anthra, by and through their agent _____ is marketing a "new therapy for the treatment of superficial bladder cancer." This incomplete presentation of the indication is misleading because it suggests a broader use of the drug than that which has been approved. Valstar is indicated for BCG refractory carcinoma in situ (CIS) of the urinary bladder when immediate cystectomy would be associated with unacceptable morbidity and mortality.

FAILURE TO PROVIDE FAIR BALANCE

Promotional materials are lacking in fair balance, or otherwise misleading if they fail to present information relating to the contraindications, warnings, precautions, and side effects associated with the use of the drug in a manner reasonably comparable to the presentation of efficacy information. The approved product labeling for Valstar lists certain precautions, warnings and adverse reactions associated with the use of the drug. However, Anthra fails to include any risk information in these materials. Presentation of a claim, representation, or the indication generally triggers the need for risk information and the dissemination of the full prescribing information.

Anthra should immediately cease using these, and all other promotional materials for Valstar that contain the same or similar claims or presentations. Anthra should submit a written response to DDMAC, on or before March 3, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Anthra should include a list of all promotional materials that were discontinued, and the discontinuation date.

Anthra should direct its response to the undersigned by facsimile at (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 Anthra that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7589 and NDA 20-892.

Sincerely,

/S/

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