NDA 20-892

Anthra Pharmaceuticals, Inc.
103 Carnegie Center, Suite 102
Princeton, NJ 08540

September 25, 1998

Attention: Timothy Urschel
Assistant Director, Regulatory Affairs

Dear Mr. Urschel:

Please refer to your new drug application (NDA) dated December 30, 1997, received December 31, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valstar™ (valrubicin) Sterile Solution for Intravesical Instillation, 5 mL Single-Use Vials (40 mg/mL).

We acknowledge receipt of your submissions dated January 19, 20, 21, 28; February 11, 17, 27; March 9, 13, 25, 26; April 6, 15, 21, 29; May 6, 13, 19, 20, 22, 28, 29; June 5, 11, 16, 26; July 24, 27, 30; August 10, 24, 28; September 2 and 9, 1998.

Your submission of June 26, 1998 extended the user fee goal date for this application to September 30, 1998.

This new drug application provides for the use of Valstar™ (valrubicin) Sterile Solution 40 mg/ml for intravesical therapy of BCG-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

We have completed the review of this application 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

An expiration dating period of 18 months is granted at this time. The expiration dating period could be extended based on real-time stability data obtained from three batches of the drug product that are manufactured using drug substance (e.g., batches 515-44-0004 and 515-44-0005 and one more batch). An expiration dating period of 24 months would be acceptable if the drug product to be marketed is manufactured using drug substance.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (immediate container and carton labels submitted July 27, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 NDA 20-892." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Ann Staten, Project Manager, at (301) 594-5770.

Sincerely,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure