DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-778 September 15, 1999

Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199

Attention: Denise S. Tindle
Regulatory Affairs Manager

Dear Ms. Tindle:

Please refer to your new drug application (NDA) dated and received December 15, 1998, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ellence (epirubicin hydrochloride injection) 50 mg/25 mL and 200 mg/100 mL single-use vials. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your pre-submission dated November 5, 1998 and your submissions dated December 21, 1998, February 12, 15, 18, 24 and 25, March 2,3, 4, 5, 22 and 25, April 6, 12, 13 and 28, May 3, 7, 11, 13, 14, 26 and 27, June 9 and 14, July 15 and 21, and Aug 25 and 30, and September 10, 1999.

This new drug application provides for the use of Ellence (epirubicin hydrochloride injection) as a component of aduvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). 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 50-778." 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 Dianne Spillman, Project Manager, at (301) 594-5746.

Sincerely,

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