DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-467/S-068/S-069
NDA 50-629/S-014/S-016

Pharmacia & Upjohn Company
Unit 0633-298-113
7000 Portage Road
Kalamazoo, MI 49001

Attention: Gregory A. Brier
Senior Regulatory Manager

Dear Mr. Brier:

Please refer to your supplemental new drug applications dated April 5, 2002, received April 8 and April 12, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Doxorubicin Hydrochloride for Injection, USP (10, 20, 50, and 150 mg), and Doxorubicin Hydrochloride Injection, USP (10, 20, 50, 75, 150, and 200 mg). 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 submissions dated January 15, 2003, January 17, 2003 and February 12, 2003 (S-069 and S-016).

Supplemental new drug applications (S-068 and S-014) provide for the use of Doxorubicin Hydrochloride for Injection and Doxorubicin Hydrochloride Injection for use in combination with cyclophosphamide as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

Supplements 069 and 016 provide for the addition of a “Geriatric Use” subsection to the PRECAUTIONS section of the labeling in compliance with 21 CFR 201.57(f)(10).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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, these submissions should be designated "FPL for approved supplements NDA 50-467/S-068/S-069 and NDA 50-629/S-014/S-016. Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Grant Williams
5/8/03 05:07:13 PM
Signed as Acting Director for Dr. Pazdur