DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-661/S-007

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 application dated September 14, 1999, received September 21, 1999, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Idamycin® (idarubicin hydrochloride for injection, USP).

This "Changes Being Effected" supplemental new drug application provides for changes to the CLINICAL PHARMACOLOGY, PRECAUTIONS and REFERENCES sections of the package insert. The package insert was revised in order to provide the same information as that in the Idamycin® PFS package insert, approved on February 17, 1997, which has the same active ingredient.

We completed the review of this supplemental new drug application and concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on September 14, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 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

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

/s/

Richard Pazdur
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