DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-661/S-008

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 November 2, 1999, received November 4, 1999, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Idamycin® (idarubicin hydrochloride for injection).

This supplemental new drug application provides 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 this application. This application is approved, effective on the date of this letter, for use as recommended with the minor editorial revisions listed below.

1. For antineoplastic agents, the Division's policy is to include only those references pertaining to handling of these agents. All other references should be deleted.

    a. In the **DOSAGE AND ADMINISTRATION** section, *Preparation of Solution* subsection, you should delete the superscript "1", at the end of the fifth paragraph.

    b. In the **DOSAGE AND ADMINISTRATION** section, *Handling and Disposal* subsection, you should change the superscripts "2-8", at the end of the second sentence, to "1-8".

    c. In the **REFERENCES** section, references 1-8 should be deleted and replaced with the updated list of references pertaining to the handling of antineoplastic agents.

        1. ONS Clinical Practice Committee. Cancer Chemotherapy Guidelines and Recommendations for Practice. Pittsburgh, Pa: Oncology Nursing Society. 1999:32-41.

        2. Recommendations for the Safe Handling of Parenteral Antineoplastic Drugs. Washington, DC; Division of Safety, Clinical Center Pharmacy Department and

Cancer Nursing Services, National Institutes of Health; 1992. US Department of Health and Human Services, Public Health Service Publication NIH 92-2621.

3. AMA Council on Scientific Affairs. Guidelines for Handling Parenteral Antineoplastics. JAMA. 1985;253:1590-1591.

4. National Study Commission on Cytotoxic Exposure - Recommendations for Handling Cytotoxic Agents. 1987. Available from Louis P. Jeffrey, Sc.D., Chairman, National Study Commission on Cytotoxic Exposure, Massachusetts College of Pharmacy and Allied Health Sciences, 179 Longwood Avenue, Boston, MA 02115.

5. Clinical Oncological Society of Australia: Guidelines and Recommendations for Safe Handling of Antineoplastic Agents. Med J Australia. 1983;1:426-428.

6. Jones RB, Frank R, Mass T. Safe Handling of Chemotherapeutic Agents: A Report from the Mount Sinai Medical Center. CA Cancer J Clin. 1983;33:258-263.

7. American Society of Hospital Pharmacists. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. Am J Hosp Pharm. 1990;47:1033-1049.

8. Controlling Occupational Exposure to Hazardous Drugs (OSHA Work-Practice Guidelines). Am J Health-Syst Pharm. 1996;53:1669-1685.

2. You should move the "Rx only" statement to the **TITLE** section of the package insert.

   Currently, the "Rx only" statement immediately precedes the **REFERENCES** section. This complies with Section 126 of FDAMA – Elimination of Certain Labeling Requirements. However, the *Guidance for Industry Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 – Elimination of Certain Labeling Requirements* (revised July 1998) indicates, on pages 3-4, that the Agency "prefers" the Rx only statement "be placed in the TITLE section of the package insert."

According to your September 27, 2002 annual report, you have discontinued marketing of Idamycin®. Should you decide to market Idamycin® again, the final printed labeling (FPL) must be identical, and include the minor editorial revisions above, to the submitted labeling (package insert submitted November 2, 1999). These revisions are terms of the approval of this application.

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, this submission should be designated "FPL for approved supplement

NDA 50-734/S-005." Approval of this submission by FDA is not required before the labeling is used.

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

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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