DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 50-577/S-014

Pharmacia & Upjohn Company
Attention: Marcia A. Greko
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Greko:

Please refer to your supplemental new drug application dated August 12, 1999, received August 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZANOSAR (streptozocin) sterile powder.

We note that this supplement was submitted as a "Special Supplement- Changes Being Effected" under 21 CFR 314.70(c).

This "Changes Being Effected" supplemental new drug application provides for the following:

1. Under the WARNINGS section, addition of a new subsection titled Renal Toxicity.
2. Under the PRECAUTIONS section, addition of text in the following three new subsections:
   - Injection-Site Reactions, Drug Interactions, Information for Patients.
   - Under the PRECAUTIONS section, change from Pregnancy Category C to Pregnancy Category D.
3. Addition of text in the DOSAGE AND ADMINSTRATION section.

We have completed the review of this supplemental application and have 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 August 12, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

However, we request you submit a Prior Approval supplement within six months addressing the following issues:

1. (b)(4)

2. (b)(4)
   (b)(4)

3.

4.

5.

6.

7.

8.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, please contact 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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