DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-297/S-024

Immunex Corporation
Attention: Nancy L. Kercher
Director, Regulatory Affairs
51 University Street
Seattle, WA 98101-2936

Dear Ms. Kercher:

Please refer to your supplemental new drug application dated April 26, 2001, received April 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Novantrone (mitoxantrone for injection concentrate).

We also refer to your submissions dated September 28, 2001, received October 1, 2001 and January 25, 2002, received January 28, 2002.

This prior approval supplemental new drug application provides for labeling changes to incorporate the risk of secondary leukemia with mitoxantrone.

We have completed the review of this supplemental 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 labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 25, 2002, patient package insert submitted January 25, 2002).

Please 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-297/S-024." Approval of this submission by FDA is not required before the labeling is used.

It is the policy of the Office of Drug Evaluation I and the Division of Oncology Drug Products to include only those references which pertain to the handling of antineoplastic agents. Reference items 1-6 should be deleted and the remaining references renumbered. Additionally, the last reference should be updated to the 1996 version. This may be implemented at the next printing.

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 call Patty Garvey, Regulatory Project Manager, at 301-594-5766.

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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