



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-212/S-008

Pfizer Incorporated
Regulatory Affairs
235 East 42nd Street 150/7/5
New York, NY 10017

Attention: Ms. Lisha Cole,
Liaison Director, Regulatory Affairs

Dear Ms. Cole:

Please refer to your supplemental new drug application dated March 19, 2004, received March 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZINECARD® for Injection (dexrazoxane for injection).

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY, PRECAUTIONS, and DOSAGE AND ADMINISTRATION** sections of the package insert submitted as fulfillment of a Postmarketing Commitment (PMC), item #7. This PMC requested that you “evaluate the pharmacokinetics of dexrazoxane in patients with hepatic and renal insufficiency.”

We acknowledge receipt of your submission dated November 19, 2004. Your submission of November 19, 2004 constituted a complete response to our September 22, 2004 action letter.

We completed our review of this application, as amended. This application is 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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-212/S-008.**" Approval of this submission 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 this product. 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, HFD-410
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/

Robert Justice
5/20/05 03:03:15 PM
Signing for Dr. Pazdur