DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-718/S-019

Johnson & Johnson Pharmaceutical Research & Development, LLC
c/o Alza Corporation
Attention: Brian Maloney, R.Ph., M.Sc.
Associate Director, Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869

Dear Mr. Maloney:

Please refer to your supplemental new drug application dated October 16, 2003, received December 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Doxil® (doxorubicin HCl liposome injection).

We acknowledge receipt of your submission dated October 28, 2003 received October 29, 2003. We also acknowledge receipt of your submission dated March 28, 2002 containing the FPL for supplement 010. We note that this FPL was superseded by the FPL for supplement 010 dated August 5, 2003 and acknowledged and retained on March 18, 2004.

This supplemental new drug application provides significant changes to the following sections of the product labeling – **BOX WARNING, WARNINGS, PRECAUTIONS (Information for the Patient), DOSAGE AND ADMINISTRATION (AIDS-KS Patients, Dose Modifications and Preparation for Intravenous Administration)**. The reference to "Doxil" has been changed "DOXIL" throughout the package insert. Also minor editorial changes were made to provide additional guidance to prescribing physicians.

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 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-718/S-019". 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857
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 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

Enclosure

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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