DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-718/S-033 **APPROVAL**

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

Dear Mr. Islam:

Please refer to your supplemental new drug application dated August 10, 2007, received August 10, 2007, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for DOXIL® (doxorubicin HCl liposome injection) single dose vial 20mg/10mL and 50mL/30mL.

We acknowledge receipt of your submissions dated May 30 and June 9 (electronic), 2008.

This supplemental new drug application provides for the use of DOXIL® (doxorubicin HCl liposome injection) single dose vial 20mg/10mL and 50mL/30mL for the treatment of AIDS-related Kaposi's Sarcoma after failure of prior systemic chemotherapy or intolerance to such therapy. This submission is intended to fulfill the postmarketing requirement to verify and describe clinical benefit.

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 50-718/S-033**." Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

We approved this NDA under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitment made under 21 CFR 314.510.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your post marketing study commitment in your submission dated May 16, 2007. This commitment is listed below.

1. To continue follow-up of safety and efficacy on clinical study MMY-3001 and to submit the final survival data and analysis as well as an updated clinical study report after at least 80% of events have occurred.

   Protocol submission: August 13, 2004
   Study start: December 20, 2004
   Final report submission: December 2011

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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
Food and Drug Administration
Suite 12B05
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 Milinda Vialpando, Regulatory Project Manager, at (301) 796-1444.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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

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