DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-718/S-028, S-029

ALZA Corporation
c/o Johnson & Johnson Pharmaceutical Research & Development, LLC
Attention: Brian J. Maloney, R.Ph, M.S.
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 November 20, 2006, received November 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DOXIL® (doxorubicin HCl liposome Injection).

We acknowledge receipt of your submissions dated January 11, 12, and 15, February 9, 13, and 20, March 13 and 20, and May 1, 10, and 16, 2007. We also refer to your submission dated July 11, 2006, supplement 028, which provided for revision of the label in order to update the WARNINGS section and to create a new subsection, Post Marketing Experience, under the ADVERSE REACTIONS section. We note that this submission has been superseded by supplement 029.

This supplemental new drug application provides for the use of DOXIL® (doxorubicin HCl liposome injection) in combination with bortezomib for the treatment of patients with multiple myeloma who have not previously received bortezomib and have received at least one prior therapy.

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.

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, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 50-718/S-029**."

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. The 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 (IND 36,778 serial number 376)
   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 post marketing study commitments must be prominently labeled "Post marketing Study Commitment Protocol", "Post marketing Study Commitment Final Report", or "Post marketing Study Commitment Correspondence."

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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-1356.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Acting Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for 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/

Ann Farrell

5/17/2007 05:04:29 PM