



NDA 50-718/S-019

NDA 50-718/S-020

Alza Corporation
c/o Johnson & Johnson Pharmaceutical Research & Development, LLC
Attention: Brian Maloney, R.Ph., M.S.
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 March 26, 2004, received March 29, 2004, 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 April 15, June 25, August 20, December 21, 2004, and January 12, 2005. We also refer to your submission dated December 1, 2004 containing final printed labeling (FPL) for supplement 019 which was approved on October 27, 2004. We note that this submission has been superseded by supplement 020. Therefore, this submission will be retained in our files.

This supplemental new drug application provides for the use of Doxil® for the treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy.

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.

Approval is based on the totality of the data presented including objective response rate, time to progression, and survival results in your randomized trial. However, the results do not conclusively demonstrate the superiority of Doxil® compared to topotecan and would not support superiority claims in any components of your marketing.

The 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-020.**" Approval of this submission by FDA is not required before the labeling is used.

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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 commitments 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.

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 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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