DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-897

Alza Corporation
Attention: Steve Ketchum, Ph.D.
Director, Regulatory Affairs
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

Dear Dr. Ketchum:

Please refer to your new drug application (NDA) dated December 17, 1997, received December 19, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ditropan® XL (oxybutinin chloride) 5 mg and 10 mg tablets.

We acknowledge receipt of your submissions dated April 30, June 30, July 30, August 6, September 15 and 30, October 27, 28 and 30, November 16 and 20, and December 4, 7, 11, 15 and 16, 1998.

This new drug application provides for the use of Ditropan XL (oxybutinin chloride) for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, immediate container and carton labels submitted December 16, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-897." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Randy Olmstead, Project Manager, at (301) 827-4260.

Sincerely,

Lisa D. Rarick, M.D.
Director, Division of Reproductive and
Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research