DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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TRANSMITTED VIA FACSIMILE

FEB 12 1999

Stephen W. Sherman
Director, Advertising and Labeling
Regulatory Affairs
Alza Corporation
1010 Joaquin Road
Mountain View, CA 94039-7210

RE: NDA 17-577
Ditropan (oxybutynin chloride) tablets
MACMIS ID #7611

Dear Mr. Sherman:

Reference is made to Alza Corporation.'s (Alza) submission of a promotional flash card (0008208) for Ditropan (oxybutynin chloride) tablets under cover of Form FDA 2253. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this submission and finds the flash card in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. DDMAC objects to the flash card for the following reasons.

Broadening of Indication

The flash card is misleading because it suggests that Ditropan is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence. Specifically, the prominent headline "It's no accident Ditropan is the most prescribed drug for incontinence" implies that the drug is indicated for patients with all types of incontinence. However, the approved product labeling (PI) for Ditropan states that the drug is indicated "...for the relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e, urgency, frequency, urinary leakage, urge incontinence, dysuria)." Ditropan is not indicated for patients with stress or overflow incontinence. The smaller bulleted claim "A standard of treatment for patients with urge urinary incontinence since 1975" is not adequate to correct this misleading message.

In order to address this objection, DDMAC requests that Alza take prompt action to correct the violations discussed in this letter and prevent their recurrence. DDMAC requests that these actions include:

Stephen W. Sherman
Alza Corporation
NDA 17-577

1. The immediate cessation of dissemination of all promotional activities and materials that contain the same or similar violations.

2. Provide to DDMAC, in writing, Alza's intent to comply with #1 above. Your response should be received by February 26, 1999.

3. This response should include a list of all similarly violative promotional materials and Alza's method for discontinuing their use.

If Alza has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Alza that only written communications are considered official.

Sincerely,

/S/

Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising, and Communications