DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 28 1997

TRANSMITTED VIA FACSIMILE

Ray Lubecki, R.Ph.
Manager, Regulatory Affairs
Alza Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

RE:

OROS (oxybutynin chloride)
MACMIS ID #5757

Dear Mr. Lubecki:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Oros (oxybutynin chloride) that are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations. DDMAC specifically refers to the press release issued by Alza Corporation (Alza) on August 13, 1997, announcing the results of two clinical trials for Oros. DDMAC finds the press release violative for the following reasons.

Pre-Approval Promotion

Section 21 CFR 312.7, states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. The press release in question is considered to be violative pre-approval promotion because it makes several claims regarding the safety and efficacy of the product. These claims include statements about the drug's specific use in the treatment of urge urinary incontinence and other claims, such as:

- "In the one study comparing OROS oxybutynin with Ditropan (oxybutynin), OROS oxybutynin was associated with less dry mouth..."
- "...OROS...demonstrated comparable efficacy and safety to immediate-release formulations of oxybutynin."

- "OROS...provided a statistically significant reduction in urge urinary incontinence episodes compared with placebo..."

In order to address these objections, DDMAC recommends that Alza take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for Oros 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 September 11, 1997.

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.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5757 in addition to the IND number.

Sincerely,

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