



JUN - 1 2000

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 20-897
Ditropan XL (oxybutynin chloride) Extended Release Tablets
MACMIS ID#: 9025

Dear Mr. Sherman:

This letter concerns Alza Corporation's (Alza) dissemination of a television broadcast advertisement for Ditropan XL (oxybutynin chloride) Extended Release Tablets. The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed this advertisement as part of its monitoring and surveillance program and concluded that it is misleading and therefore violates the Federal Food, Drug, and Cosmetic Act and applicable regulations. Our specific objections follow.

Presentation of Discontinuation Rates Minimizes Overall Presentation of Risk Information

"In studies, the most common side effect was dry mouth. Only 1% of patients stopped taking Ditropan XL for that reason. Other side effects may include constipation, drowsiness, blurred vision, dizziness, diarrhea, and nausea. Only 7% of patients discontinued due to side effects."

The discontinuation statements included in your advertisement are selective presentations of the disclosed side effects that minimize the overall presentation of this risk information. For instance, the statement that only 1% of patients discontinued drug treatment because of dry mouth is misleading because the ad does not also disclose that 61% of patients in clinical trials on Ditropan XL experienced dry mouth. Therefore, the presentation of these discontinuation rates without accompanying contextual information is misleading.

On January 12, 1999, DDMAC raised this contextual risk disclosure issue to Alza in written comments on a proposed professional sales aid for Ditropan XL.

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Alza should immediately cease using this television advertisement and all other promotional materials for Ditropan XL that similarly minimize this side effect information in other presentations. We should receive your written response no later than June 15, 2000, and it should list similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

Your response should be directed to Mark W. Askine, R.Ph., by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Alza that only written communications are considered official.

In all future correspondence, regarding this matter, please refer to MACMIS ID# 9025 in addition to the NDA number.

Sincerely,

/S/

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

/S/

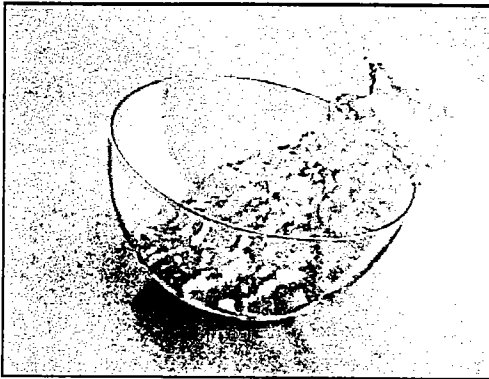
Joan Hankin, J.D.
Consumer Safety Officer
Division of Drug Marketing,
Advertising, and Communications

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DITROPAN[®] XL
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*OPEN ON BOWL ANIMATION.
SUPER: SYMPTOMS OF OVERACTIVE BLADDER MAY
INCLUDE: WETTING ACCIDENTS, STRONG NEED TO
URINATE, AND URINATING OFTEN.*

ANNCR VO: If you have wetting accidents,
sudden urges to urinate, or urinate often,



PULL IN TIGHT TO BOWL AS IT BEGINS TO TIP.

ANNCR VO: you may have symptoms of
overactive bladder.



CUT TO WOMAN HIKING UP HILL.

ANNCR VO: But they could be symptoms of
other medical conditions.



CUT TO COUPLE IN GOLF CART.

ANNCR VO: If your doctor determines that you do
have overactive bladder,

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CUT TO TEACHER IN CLASSROOM.
SUPER: DITROPAN XL® LOGO.

ANNCR VO: now it can be treated with prescription
DitropanXL®.



CUT BACK TO HIKER.

ANNCR VO: Ditropan XL® is the only once-a-day
medication for overactive bladder.



CUT BACK TO GOLF COUPLE.
SUPER: FOR MORE INFORMATION ABOUT DITROPAN XL®,
TALK TO YOUR DOCTOR OR PHARMACIST.

ANNCR VO: For more information, call: 1-888-395-1232.



CUT TO WOMAN IN GROCERY STORE.

ANNCR VO: If you have certain types of stomach,
urinary, or glaucoma problems, you should
not take Ditropan XL®.



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SUPER: CALL TOLL-FREE 1-888-395-1232



ANNCR VO: In studies, the most common side effect was dry mouth. Only 1% of patients stopped taking Ditropan XL® for that reason.



SUPER: SEE OUR AD IN NEW CHOICES.

ANNCR VO: Other side effects ^{may} include constipation, drowsiness, blurred vision, ~~dizziness~~, and nausea. Only 7% of patients discontinued due to side effects.
diarrhea



CUT BACK TO GOLFERS AS WOMAN IS ABOUT TO SWING.

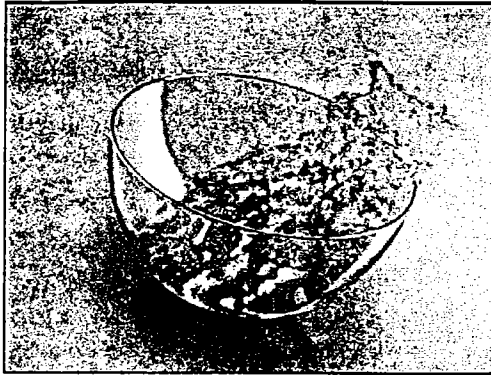
ANNCR VO: Ask your doctor about



SUPER: DITROPAN XL® LOGO.

ANNCR VO: once-a-day Ditropan XL®...

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CUT BACK TO BOWL ANIMATION.

ANNCR VO: because an overactive bladder can be
an accident waiting to happen.



CUT BACK TO FIRST WOMAN.

WOMAN: My doctor prescribed Ditropan XL[®].



WOMAN: It's the only once-a-day medication



SUPER: PHONE NUMBER AND WEB SITE.

WOMAN: for overactive bladder.