



FOI

MAR 27 1997

TRANSMITTED VIA FACSIMILE

Nicholas J. Troise
Senior Regulatory Specialist
Zeneca Pharmaceuticals
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

RE: NDA# 20-498
Casodex (bicalutamide)
MACMIS ID #5168

Dear Mr. Troise:

Reference is made to Zeneca Pharmaceuticals' (Zeneca) May 9, 1996, submission to the Division of Drug Marketing, Advertising and Communications (DDMAC) containing a visual aid for Casodex (bicalutamide) with the tag-line "The once-daily choice in antiandrogen therapy." Reference is also made to DDMAC's letter to Zeneca dated May 15, 1996, stating that DDMAC had no objections to the visual aid at the time.

Pursuant to the provisions of CFR 202.1 (j) (4), we are informing Zeneca that DDMAC has changed its opinion and has determined that the tag-line "The once-daily choice in antiandrogen therapy" is misleading. This determination is based on the fact that there is now another antiandrogen that is also dosed once a day. Further, the approval of this agent occurred after DDMAC's May 15, 1996, comments to Zeneca. DDMAC requests the claim be revised in light of this occurrence.

Because these comments constitute a change in DDMAC's position, Zeneca will be provided a reasonable period of time to make this revision. Accordingly, this revision should be completed within 90 days of receipt of this letter. Please notify DDMAC in writing of the specific date that this revision is complete.

If Zeneca 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 Zeneca that only written communications are considered official.

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In all future correspondence regarding this particular matter, please refer to
MACMIS ID #5168 in addition to the NDA number.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark W. Askine". The signature is written in a cursive style with a large initial "M".

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

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File Name:casodex\mar26nov.let

Drafted: Askine Date: 3/26/97
Concur: Palmer Date: 3/26/97

CC:
HFD-40/NDA #20-498
HFD-40/Chron/Askine/Palmer
HFD-580/Fourcroy/Jolson
HFD-580/NDA #20-498

MACMIS ID #5168

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

Close Out: YES

FOI Status: Releasable