



*FBI*

Food and Drug Administration  
Rockville MD 20857

MAY 6 1997

**TRANSMITTED VIA FACSIMILE**

Jill Lynch  
Regulatory Affairs Specialist, Advertising  
Abbott Laboratories  
Dept. 491, Bldg. AP6B-1  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

**RE: NDA 20-223**  
Hytrin (terazosin HCl) capsules  
MACMIS ID #5382

Dear Ms. Lynch:

Reference is made to Abbott Laboratories' (Abbott) April 21, 1997, FDA Form 2253 submission consisting of two journal advertisements for Hytrin (terazosin HCl) capsules. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these materials and finds the journal ad identified as 6105017582C to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Specifically, the advertisement in question makes a graphical representation about the use and efficacy of the product, and is not accompanied by either the full prescribing information or a brief summary.

The dissemination or publication of this journal advertisement, and all similarly violative materials, should be discontinued immediately upon receipt of this letter. Abbott should respond to this letter in writing by May 20, 1997. Abbott's response should include a list of all similarly violative materials and a description of the method for discontinuing their use.

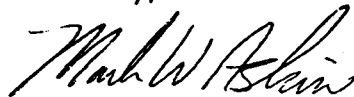
If Abbott has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Abbott that only written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

Jill Lynch  
Abbott Laboratories  
NDA 20-223

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In all future correspondence regarding this particular matter, please refer to  
MACMIS ID #5382 in addition to the NDA number.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark W. Askine".

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

Jill Lynch  
Abbott Laboratories  
NDA 20-223

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File Name: Hytnov.let

Drafted: Askine                      Date: 4/30/97  
Concur: O'Brien                      Date: 5/2/97

CC:  
HFD-40/NDA # 20-223  
HFD-40/Chron/Askine/Palmer  
HFD-580/Fourcroy/Jolson  
HFD-580/NDA #20-223

MACMIS ID # 5382

MACMIS Type Code: LETT  
MACMIS Action Code: VIOL

2253 ID#: 52353

Material ID#(s): 6105017582C

Due Date: May 20, 1997

Close Out: NO

FOI Status: Releasable