DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JUN 10 1997

TRANSMITTED VIA FACSIMILE

Jill Lynch, R.Ph.
Regulatory Affairs Specialist
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500

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

Dear Ms. Lynch:

Reference is made to Abbott Laboratories' (Abbott) May 20, 1997, response to the Division of Drug Marketing, Advertising and Communications' (DDMAC) May 6, 1997, letter objecting to a journal advertisement for Hytrin (terazosin).

DDMAC has reviewed Abbott's response and notes that future use of the ad in question will be accompanied by the appropriate brief summary or full prescribing information (PI). DDMAC also notes that Abbott has submitted a list of promotional materials that have been discontinued pending addition of the brief summary or PI.

DDMAC, however, is not persuaded by Abbott's contention that the balloon itself does not "convey any recognizable use or indication." As you know, the requirements for reminder advertisements state that these types of ads may contain "...written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug product." It is DDMAC's position that the graphic image of the clothes pin clamped balloon makes a representation about Hytrin. Therefore, as stated in our discussion on May 7, 1997, the Hytrin balloon art included in attachments A and B of your submission is violative. Further, DDMAC notes that Abbott's April 21, 1997, FDA Form 2253 submission contains similarly violative advertisements (6115017775B, 6115017775C) that make graphical representations about the product and are lacking the appropriate brief summary or PI.

The dissemination or publication of these journal advertisements, and all similarly violative materials, should be discontinued immediately upon receipt of this letter.

Abbott should respond to this letter in writing by June 24, 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.

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

Sincerely,

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