DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 19-057/S-015
NDA 20-347/S-006

Abbott Laboratories
Attention: Ms. Marilou Reed
D-491/AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-6108

Dear Ms. Reed:

Please refer to your supplemental new drug applications dated June 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hytrin (terazosin HCl) 1, 2, 5 and 10 mg Tablets (NDA 19-057), Hytrin (terazosin HCl) 1, 2, 5 and 10 mg Soft Elastic Capsules (NDA 20-347).

We acknowledge receipt of your submissions dated July 27 and December 6, 2001 to each NDA.

These "Changes Being Effected" supplemental new drug applications provide for final printed labeling with the following revisions:

NDAs 19-507 & 20-347

Under ADVERSE REACTIONS, the Post-marketing Experience subsection has been moved to below Table 4 and revised from:

Post-marketing Experience
Post-marketing experience indicates that in rare instances patients may develop allergic reactions, including anaphylaxis, following administration of HYTRIN tablets. There have been reports of priapism during post-marketing surveillance.

To:

Post-marketing Experience
Post-marketing experience indicates that in rare instances patients may develop allergic reactions, including anaphylaxis, following administration of terazosin hydrochloride. There have been reports of priapism and thrombocytopenia during post-marketing surveillance. Atrial fibrillation has been reported.

NDA 19-057

Under HOW SUPPLIED, the phrase, “Abbo-Pac unit dose strip packages of 100 tablets” has been removed for each dosage strength and a phrase indicating the Abbott symbol and Abbo-Code has been added for each dosage strength.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the final printed labeling included in your June 26, 2001 submissions. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky
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