**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-057/S-021 and 20-347/S-009

Abbott Laboratories
Attention: Ms. Alison Hayles
Dept. RA76/Blg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Hayles:

Please refer to your supplemental new drug applications dated August 31, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hytrin (terazosin hydrochloride) Tablets (NDA 19-057) and Hytrin (terazosin hydrochloride) Capsules (NDA 20-347).

These supplemental new drug applications provide for revisions to the package insert (PI) as follows:

1. In the **PRECAUTIONS** section, the following subsection was added after "**Prostatic Cancer**":

   **Intraoperative Floppy Iris Syndrome (IFIS)**
   Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients on/or previously treated with alpha-1 blockers. This variant of small pupil syndrome is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's ophthalmologist should be prepared for possible modifications to their surgical technique, such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances. There does not appear to be a benefit of stopping alpha-1 blocker therapy prior to cataract surgery.

2. In the **ADVERSE REACTIONS**/**Post-marketing Experience** section, the following was added as a second paragraph:

   During cataract surgery, a variant of small pupil syndrome known as Intraoperative Floppy Iris Syndrome (IFIS) has been reported in association with alpha-1 blocker therapy (see PRECAUTIONS).

3. In the **DOSAGE AND ADMINISTRATION**/**Benign Prostatic Hyperplasia**/**Use with Other Drugs** section, the following was added as the last sentence of the paragraph:

   Hypotension has been reported when Hytrin has been used with phosphodiesterase-5 (PDE-5) inhibitors.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 31, 2005).

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Melissa Robb, Regulatory Project Manager, at (301) 796-1138.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

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/s/

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Norman Stockbridge

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