



NDA 19-057/S-022

Abbott Laboratories
Attention: Ms. Jennifer Doney
AP 30-1E Dept. PA76
200 Abbott Park Road
Abbott Park, IL 60064-6157

SUPPLEMENT APPROVAL

Dear Ms. Doney:

Please refer to your New Drug Application (NDA), approved August 7, 1987, for Hytrin (terazosin hydrochloride) 1, 2, 5, and 10 mg Tablets.

We also refer to our supplement request letter dated June 2, 2009.

Your supplemental new drug application provides for the following revisions to the labeling for Hytrin (terazosin hydrochloride) consistent with our June 2, 2009, request letter:

1. Add the following text to the **PRECAUTIONS/Drug Interactions** section of the package insert:

Concomitant administration of HYTRIN with a phosphodiesterase-5 (PDE-5) inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension (see **DOSAGE AND ADMINISTRATION**).

2. Change the following text in the **DOSAGE AND ADMINISTRATION/Use with Other Drugs** section of the package insert:

FROM

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

TO

Concomitant administration of HYTRIN with a PDE-5 inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension; therefore PDE-5 inhibitor therapy should be initiated at the lowest dose in patients taking HYTRIN.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “**SPL for approved NDA 19-057/S-022.**”

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Dan Brum, PharmD, MBA, RAC, Regulatory Project Manager, at (301) 796-0578.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling text

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

/s/

Mary Southworth
7/10/2009 11:55:37 AM