



NDA 19-815/S-007

Shire Laboratories Inc.
c/o Shire Pharmaceutical Development Inc.
Attention: Raj Kishore, Ph.D
1801 Research Blvd. Suite 600
Rockville, MD 20820

Dear Dr. Kishore:

Please refer to your supplemental new drug application dated March 31, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ProAmatine (midodrine hydrochloride) 2.5 mg, 5 mg, and 10 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised as follows:

1. Under **CLINICAL PHARMACOLOGY, Pharmacokinetics**, a new subheading was added entitled: "**Special Populations**" with the following language:

A study with 16 patients undergoing hemodialysis demonstrated that ProAmatine is removed by dialysis.

2. **Minor revisions** were noted; under **HOW SUPPLIED:**

Manufacturer information was updated from previous address of 7900 Tanners Gate Drive, Florence, KY, 41042, USA, has been changed to One Riverfront Place, Newport, KY, 41071, USA.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 31, 2004.

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, HFD-410
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 feel free to call:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS
Regulatory Health Project Manager,
(301) 594.5315.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D
Acting 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
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/s/

Norman Stockbridge
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