DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-815/S-005

Shire Laboratories Inc.
Attention: Zohra E. Lomri
1550 East Gude Drive
Rockville, MD 20850

Dear Ms. Lomri:

Please refer to your supplemental new drug application dated April 12, 2001, received April 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ProAmatine (midodrine hydrochloride) 2.5 mg and 5 mg Tablets.

We acknowledge receipt of your submissions dated November 20, 2001 and March 14, 2002. Your submission of November 20, 2001 constituted a complete response to our August 13, 2001 action letter.

This supplemental new drug application provides for ProAmatine 10 mg tablets as an additional strength to the existing 2.5 mg and 5 mg strengths.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

Please provide final printed labeling (FPL) identical to the submitted draft labeling (package insert submitted November 20, 2001, immediate container and carton labels submitted November 20, 2001) in your next annual report.

Please submit one market package of the drug product when it is available.

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, call Edward Fromm, Regulatory Project Manager, at (301) 594-5313.

Sincerely,

{See appended electronic signature page}
Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar

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