**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-049/S-015

Shire Pharmaceutical Development Inc.
Attention: Raj Kishore, Ph. D.
Senior Director, Regulatory Affairs
1801 Research Blvd., Suite 600
Rockville, MD 20850

Dear Kishore:

Please refer to your supplemental new drug application dated March 8, 2004, received March 8, 2004 submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Pentasa® (meslamine) Controlled Release Capsules, 250 mg.

We acknowledge receipt of your submission dated July 6, 2004 containing requested blister package labeling.

This supplemental new drug application provides for the addition of a new strength (500 mg capsule).

We completed our review of this application, as amended. This application is approved on draft labeling, effective the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

Listed changes

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the 1) draft package insert submitted March 8, 2004 ((b)(4)----------, 2) draft sample package carton submitted March 8, 2004 identified (b)(4)---------- ---------- -, 3) draft carton label submitted March 8, 2004 identified (b)(4)------ ---- ---------- , 4) draft container label submitted March 8, 2004 identified (b)(4)----------, (b)(4)-------, and 5) draft blister label submitted July 6, 2004 (b)(4)----------

1. Draft Package Insert ((b)(4)---------- ----------):
   a. The "prescribing information as of date" should be updated from June 1999.
   b. Change the "Rx" to read "Rx only" in the package insert.

2. Draft Sample Pack Carton identified(b)(4)---------- ---------- -:
   The "250 mg" on the side panel should be updated to read "500 mg".

3. The word "capsules" should follow the words "controlled-release" wherever the established name appears on all carton sizes.

These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-049/S-015". Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Betsy Scroggs, Pharm.D., Consumer Safety Office at (301) 827-1250.

Sincerely,

*{See appended electronic signature page}*

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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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Robert Justice
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