DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-049/S-019

Shire Development, Inc.
Attention: Nurit Rojstaczer, Ph.D.
Manager, Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Dr. Rojstaczer:

Please refer to your supplemental new drug application dated December 22, 2006, received December 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pentasa (mesalamine) Controlled-Release Capsules, 250 mg and 500 mg.

We acknowledge receipt of your submissions dated March 5 and June 7, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the Pentasa package insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 22, 2006.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kristen Everett, Regulatory Project Manager, at (301) 796-0453.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick
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