DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-049/S-017

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 January 9, 2006, received January 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pentasa® (mesalamine) Controlled-Release Capsules 250 mg.

We acknowledge receipt of your submission dated May 16, 2006.

This "Changes Being Effected" supplemental new drug application provides for revision of the unit-dose blister card labeling.

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

The unit-dose blister card must be identical to the unit-dose blister card submitted on May 16, 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
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/

Brian Harvey
6/27/2006 10:58:39 AM