DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-618/S-016

Solvay Pharmaceuticals, Inc.
Attention: Michael F. Hare
Manager, Regulatory Affairs
901 Sawyer Road
Marietta, Georgia 30062

Dear Mr. Hare:

Please refer to your supplemental new drug application dated June 23, 2005, received June 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ROWASA® (mesalamine) 4g/60mL Rectal Suspension Enema.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to include additional safety statements to the PRECAUTIONS and ADVERSE REACTIONS sections of the label.

We completed our review of this supplemental new drug application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 23, 2005.

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
12/29/2005 08:58:22 AM
My original signed off of this supplement letter was
on 12/21/05.