DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-618/S-018

Alaven Pharmaceutical LLC
Attention: Lindsey Brown
Senior Manager of Regulatory Affairs
2260 Northwest Parkway Suite A
Marietta, GA 30067

Dear Ms. Brown:

Please refer to your supplemental new drug application dated and received February 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rowasa® (Mesalamine) Rectal Suspension Enema, 4.0 g/6.0 mL.

We acknowledge receipt of your submissions dated May 12, May 19, and June 16, 2008.

This supplemental new drug application provides for a new, sulfite-free formulation of the drug product and for a new, fourteen unit packaging configuration. This supplement also provides for new trade name "sfROWASA (mesalamine) Rectal Suspension 4 g/60 mL", and new labeling.

We completed our review of this 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 June 16, 2008.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Gastroenterology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Suite 12B05
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 Heather Buck, Regulatory Project Manager, at (301) 496-1413.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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