DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 14 1997

TRANSMITTED VIA FACSIMILE

Sherry N. Corson
Solvay Pharmaceuticals
581 Main Street
Marietta, GA 30062

Re: NDA 19-618
Rowasa (mesalamine) Rectal Suspension Enema
MACMIS File ID #5595

Dear Ms. Corson:

This letter is in reference to Solvay Pharmaceuticals' (Solvay) submission, dated June 27, 1997, of promotional materials under cover of FDA Form 2253 for Rowasa (mesalamine) Rectal Suspension Enema. This submission included a promotional brochure, a promotional card, two leaflets, and a compact road atlas. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regard the promotional brochure and card to be in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

DDMAC's specific objections are that the brochure promotes the use of Rowasa for unapproved uses and that it fails to present a fair balance between information relating to the side effects and contraindications and information relating to the effectiveness of the drug. The approved product labeling for Rowasa states that it is "indicated for the treatment of active mild to moderate distal ulcerative colitis, proctasigmoiditis, or proctitis. However, the promotional brochure and card refer to ulcerative colitis, without any reference to the limitations to its use only in mild to moderate distal cases. Thus, Solvay is implying that Rowasa is effective in all types of ulcerative colitis, including both proximal and severe cases, when such has not been demonstrated by substantial evidence.

Moreover, the promotional brochure fails to present a fair balance between information relating to the side effects associated with the use of the drug and information relating to the effectiveness of the drug. Solvay states that Rowasa is "usually well tolerated with most side effects mild and transient" but fails to present the most frequently observed adverse events associate with the use of this drug, such as abdominal cramps, gas, fever, flu symptoms, and leg/joint pain. Therefore, this brochure is misleading.

Solvay should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter. Solvay should

submit a written response to DDMAC on or before July 28, 1997, describing the steps that it has taken to ensure that these activities and the use of these materials have been suspended.

Solvay should address any correspondence or additional questions to the undersigned at the Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17 B-17, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Solvay that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #5595, in addition to the NDA number.

Sincerely,

Stephen W. Sherman

Stephen W. Sherman
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications