DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 7-073/SLR-120

Pharmacia & Upjohn Company
Attention: Tammy Sanders
Senior Regulatory Manager
7000 Portage Road
Kalamazoo, Michigan 49002

Dear Ms. Sanders:

Please refer to your supplemental new drug application dated, October 19, 2000 received October 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AZULFIDINE™ (sulfasalazine) Tablets and EN-tabs™ 500 mg.

We acknowledge receipt of your submissions dated January 31, 2002. Your submission of January 31, 2002 constituted a complete response to our July 2, 2001 action letter.

This supplemental new drug application provides for revision to the DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE AND DOSAGE AND ADMINISTRATION sections for the AZULFIDINE™ Tablet package insert for the 100-count and 300-count packages in order to harmonize the AZULFIDINE™ Tablet insert with the AZULFIDINE EN-tabs™ insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling package insert submitted January 31, 2002, and immediate container labels submitted January 31, 2002. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Betsy Scroggs, Pharm. D., Consumer Safety Officer at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug 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/

Victor Raczkowski

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