CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-243

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-243

Pharmacia & Upjohn
Attention: Gregory A. Brier
Regulatory Manager – Marketed Products
7000 Portage Road
Kalamazoo, Michigan 49001-0199

AUG 18 2000

Dear Mr. Brier:

Please refer to your new drug application (NDA) dated October 15, 1999, received October 18, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azulfidine (sulfasalazine tablets) Tablets, 500 mg.

We acknowledge receipt of your submissions dated March 30; May 19, 25, and 30; June 6; and August 2 and 11, 2000.

This new drug application provides for the use of Azulfidine (sulfasalazine tablets) Tablets, 500 mg.

We have completed the review of this 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-243." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your post-marketing commitment specified in your submission dated August 11, 2000. This commitment, along with any completion dates agreed upon, is stated below.

To obtain pharmacokinetic data relevant to children with juvenile rheumatoid arthritis, a post-marketing pharmacokinetic study will be conducted in a suitable number of pediatric patients with juvenile rheumatoid arthritis; or in lieu of such a study, sufficient information from

literature and other sources will be submitted that adequately addresses this issue within one year of the approval date.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your post-marketing commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these post-marketing commitments must be clearly designated "Post-marketing Commitments."

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement at this time. We are waiving the pediatric study requirement for pediatric patients below six years of age for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division, one copy to the Division of Gastrointestinal and Coagulation Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division Gastrointestinal and Coagulation Drug Products.

If you have any questions, call Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely,

/S/

Karen Midthun, M.D.
Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure