CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-049/S006

APPROVAL LETTER

NDA 20-049/S-006

Roberts Laboratories Inc.
Attention: Richard J. Raffa
Associate Director, Regulatory Affairs
4 Industrial Way West
Eatontown, NJ 07724-2274

SEP 10 1999

Dear Mr. Raffa:

Please refer to your supplemental new drug application dated November 20, 1998, received November 23, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pentasa (mesalamine) Capsules.

We acknowledge receipt of your submission dated August 6, 1999. Your submission of August 6, 1999 constituted a complete response to our May 12, 1999 action letter.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c). However, as we notified you in our December 15, 1998 letter to this application, the proposed changes are not the kind of changes permitted by regulation to be put into effect prior to approval of a supplement. Therefore, the supplement was reviewed under 21 CFR 314.70(b).

This supplemental new drug application provides for the following changes to the package insert:

1. Revision of the ADVERSE REACTIONS section to,

   a. add a Postmarketing Reports subsection, as requested in our September 1, 1998 letter,

   b. add "agranulocytosis" as an additional adverse event in the **Other:** subsection, and

   c. add a statement that "Allergic reactions, which could involve eosinophilia, can be seen in connection with PENTASA therapy," as requested in our August 25, 1998 letter.

2. Revision of the PRECAUTIONS section, Carcinogenesis, Mutagenesis, Impairment of Fertility subsection to include results from 104-week feeding studies in mice and rats.

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 August 6, 1999). 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 Practitioner" 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, contact Melodi McNeil, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

/S/ 9-10-99 /S/ 9/10/99

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL