CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 019651/S005

APPROVAL LETTER

NDA 19-651/S-005

AUG 19 1997

Procter & Gamble Pharmaceuticals, Inc.
Attention: Melanie A. Bruno, Ph.D., M.B.A.
11450 Grooms Road
SW GR CNE75
Cincinnati, OH 45242-1408

Dear Dr. Bruno:

Please refer to your supplemental new drug application dated June 4, 1996, received June 5, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Asacol (mesalamine) Tablets.

We acknowledge receipt of your submissions dated June 17, July 3, and August 5, 1997. The User Fee goal date for this application is February 6, 1998.

The supplemental application provides for a new indication, the maintenance of remission of ulcerative colitis.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on August 5, 1997. Accordingly, the supplemental application is approved effective on the date of this letter. As discussed in the August 18, 1997 telephone conversation between you and Ms. Melodi McNeil of this Division, please revise the first sentence of the bolded statement in the PRECAUTIONS section, Renal subsection to read,

> "Therefore, caution should be exercised when using Asacol (or other compounds which contain or are converted to mesalamine or its metabolites) in patients with known renal dysfunction or history of renal disease."

This revision may be made at the next printing of the insert.

In addition, please submit three copies of the introductory promotional material 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 and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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, please contact Melodi McNeil, Regulatory Health Project Manager, at (301) 443-0483.

Sincerely yours,

/S/ 8-18-97

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

cc:
Original NDA 19-651
HFD-180/Div. files
HFD-180/CSO/M.McNeil
HFD-180/Prizont
HFD-180/Shaw
HFD-180/Choudary
HFD-720/Huque
HFD-720/Chen
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFI-20/Press Office (with labeling)

APPEARS THIS WAY
ON ORIGINAL

Drafted by: mm/August 18, 1997/c:\wpfiles\cso\n\19651708.ap
final: August 18, 1997

APPROVAL (AP)

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.