DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-830 **NDA APPROVAL**

Procter & Gamble Pharmaceuticals
Attention: Christian A. Bernhardt, Ph.D.
Director, Regulatory Affairs for GI Category
Mason Business Center
8700 Mason Montgomery Road
Mason, OH 45040-9462

Dear Dr. Bernhardt:

Please refer to your new drug application (NDA) dated and received October 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for [TRADENAME] (mesalamine) Delayed-Release Tablets, 800 mg.

We acknowledge receipt of your submissions dated November 2, 2004, December 9, 2004, and January 14, February 17, February 24, February 28, March 3, March 9, March 28, April 27, May 9, May 12, May 13, May 17, June 9, June 16, July 11, July 13, August 2, August 12, and August 15, 2005., October 22, 2007, and December 11, January 29, February 13, February 22, February 25, March 4, 2008, and April 11, 2008.

The October 22, 2007, submission constituted a complete response to our August 29, 2005, action letter.

This new drug application provides for the use of [TRADENAME] (mesalamine) Delayed-Release Tablets for the treatment of moderately active ulcerative colitis.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We acknowledge your May 28, 2008, submission including final printed labeling (FPL) for your package insert. We have reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format. Please note that any post-approval submissions including a prior approval supplement with your proposed tradename, should also include revised labeling for the package insert.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 11, 2008, submission containing final printed carton and container labels. Please note that your prior approval supplement with your proposed tradename should also include revised carton and container labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed package insert labeling submitted May 28, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-830."

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

As notified by the Discipline Review Letter sent to you on April 18, 2008, we found your proposed tradename [redacted] unacceptable. If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 4 years because studies are impossible or highly impractical due to the small number of pediatric ulcerative colitis patients less than 5 years of age.

We are deferring submission of your pediatric study for ages 5 to 17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below:

1. Conduct a study in pediatric patients ages 5 to 17 years with ulcerative colitis using an age-appropriate formulation (i.e., an oral mesalamine formulation appropriate for pediatric dosing), such as your approved product, Asacol®. The study will evaluate the pharmacokinetics, safety, and clinical response of pediatric patients undergoing six weeks of oral mesalamine therapy. The study will be a randomized, double-blind study comparing at least two different dose levels of mesalamine and it will enroll at least 40 pediatric patients in each dosing arm.

Per our discussion on May 28, 2008, we acknowledge your goal to complete the study according to the following schedule:

Protocol Submission	August 15, 2008
Study Start Date:	October 15, 2008
Study Completion Date:	November 13, 2010
Final Report Submission:	January 15, 2011

Submit final study reports to this NDA, 21-830. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment**".

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Division Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Final product labeling for package insert attached

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Donna Griebel

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