DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-229

The Proctor and Gamble Co.
Attention: Linda Jones
Director, Regulatory Affairs
8700 Mason-Montgomery Road
Mason, Ohio 45040-9462

Dear Ms. Jones:

Please refer to your new drug application (NDA) dated January 27, 2000, received January 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec OTC (omeprazole magnesium delayed-release tablets, 20 mg).

We acknowledge receipt of your submissions dated December 20, 2002, February 24, March 7, and June 12 and 19, 2003. Your submission of December 20, 2002, constituted a complete response to our August 8, 2002, action letter.

This new drug application provides for over-the-counter use of omeprazole magnesium delayed-release tablets for the treatment of frequent heartburn for consumers 18 years of age and older.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (14-, 28-, and 42-count package carton labeling and consumer information leaflet submitted on June 19, 2003, and 2-count sample package labeling, plastic overlay for the 42-count package, and unit-dose blister labeling submitted on June 12, 2003), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-229**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one copy to the Division of Gastrointestinal and Coagulation Drug Products and the other copy, along with the approved labeling, to the Division of Over-the-Counter Drug Products, HFD-560.

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

We remind you of the following considerations for appropriate marketing of this product.

1. (B4)

2. We are approving 28- and 42-count package sizes for this product amid concerns that consumers follow instructions that limit duration of use to 14 consecutive days and frequency of use to not more than 3 courses in a given year. If you recall, much of the discussion of the June 2002 joint meeting of the Nonprescription and Gastrointestinal Advisory Committees focused on the issue of appropriate duration and frequency of use. The joint committees recommended a course of therapy no longer than 14 consecutive days and no more than 3 courses per year, and we have followed these recommendations. By proposing these 28- and 42-count package sizes configured as multiple 14-count units, we feel that consumers may better understand the limitations of use. However, if you should be interested in marketing other package configurations in the future (e.g., bottles containing greater than 14 capsules), we will expect submission of a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of the limitations of use. You are encouraged to contact the Division of Over the Counter Drug Products about the content and format of such a supplement prior to submission.

We agree with your plans to distribute the 2-count trial package only to consumers who have frequent heartburn, as defined in the approved labeling, as outlined in your December 20, 2002, submission.

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

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, contact Laura Shay, Regulatory Project Manager, at 301-827-2274.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Florence Houn, M.D., M.P.H.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures

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