DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-823

Procter & Gamble Pharmaceuticals, Inc.
Attention: Linda Manning, Pharm.D.
U.S. Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Manning:

Please refer to your new drug application (NDA) dated August 30, 2004, received August 31, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel With Calcium (risedronate sodium 35 mg and calcium carbonate 1250 mg) Tablets.

We acknowledge receipt of your submissions dated September 29, and December 6, 2004, and January 13, March 14, May 17, and 20, June 17, 21, 24, July 1, 18, 25, 26, and 29, and August 10, 2005.

This new drug application provides for the use of Actonel With Calcium for the prevention and treatment of osteoporosis in postmenopausal women.

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 stability data reviewed supports a 36-month expiry for Actonel, and 48-months for calcium carbonate. The expiration date for each co-package of Actonel With Calcium will be the earliest expiration date of either of the component products used in the co-package.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for package insert and patient package insert submitted July 29, 2005, and immediate carton labels submitted August 10, 2005). Marketing this product with FPL that is not identical to the approved labeling text 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*. In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html. For administrative purposes, designate this submission "**FPL for approved NDA 21-823**." Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division 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 Land
Rockville, MD 20857

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, please call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Eric Colman
8/12/05 03:54:09 PM
Eric Colman for David Orloff