DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-835/S-022 & S-023

Procter & Gamble Pharmaceuticals, Inc.
Attention: Gricelly Vargas, Ph.D.
U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040

Dear Dr. Vargas:

Please refer to your supplemental new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated and received October 20, 2005 (NDA 20-835/S-022), and dated March 16, 2006, and received March 17, 2006 (NDA 20-835/S-023), for Actonel (risedronate sodium) Tablets.

We acknowledge receipt of your submissions dated December 21, 2005, and February 1 and 10, June 15, July 20, and August 4 and 10, 2006.

These supplemental new drug applications provide for:

NDA 20-835/S-022	A new indication to support the use of Actonel 35 mg once a week for the treatment of osteoporosis in men.
NDA 20-835/S-023	An updated patient package insert (PPI) to align the Actonel PPI with the Actonel With Calcium PPI.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 10, 2006.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and patient package insert submitted August 10, 2006). 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 20-835/S-022 & S-023**." 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 these applications.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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 inserts directly 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

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, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 796-1224.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology 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/

Mary Parks

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