DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-835/S-019
NDA 21-823/S-002

Procter & Gamble Pharmaceuticals, Inc.
Attention: Gary Galletta, Pharm.D.
Associate Director, U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040

Dear Dr. Galletta:

Please refer to your supplemental new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated March 23, 2005, received March 24, 2005, for Actonel (risedronate sodium) Tablets (NDA 20-835/S-019), and dated December 22, 2005, received December 23, 2005 for Actonel With Calcium (risedronate sodium 35 mg and calcium carbonate 1250 mg) Tablets (NDA 21-823/S-002).

We acknowledge receipt of your submissions dated September 8, 2005, and January 9, and 18, 2006, to NDA 20-835, and January 19, 2006, to NDA 21-823.

These supplemental new drug applications provide labeling information concerning the use of risedronate administered once a week in the prevention of osteoporosis in postmenopausal women.

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 January 18, 2006, to NDA 20-835 and January 19, 2006 to NDA 21-823.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 18, 2006, to NDA 20-835 and January 19, 2006 to NDA 21-823). 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-019, and NDA 21-823/S-002**." Approval of this submission by FDA is not required before the labeling is used.

NDA 20-835/S-019
NDA 21-823/S-002

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.
Acting 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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