DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-823/S-004

Procter & Gamble Pharmaceuticals
Attention: Kathleen Blieszner, Ph.D.
U. S. Regulatory Affairs
Mason Business Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Blieszner:

Please refer to your supplemental new drug application dated February 27, 2006, received February 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel with Calcium (risedronate sodium tablets with calcium carbonate tablets) Tablets.

We acknowledge receipt of your submission dated August 3, 2006.

This supplemental new drug application provides for adding two sentences concerning eye inflammation and osteonecrosis of the jaw to the **Post-marketing Experience** subsection of the **ADVERSE REACTIONS** section of the package insert, and to the **What are the possible side effects of Actonel?** section of the patient package insert.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 3, 2006 (package insert and patient package insert).

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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