DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-823/S-003

Procter & Gamble Pharmaceuticals
Attention: Katherine McNeal
U. S. Regulatory Affairs
Mason Business Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. McNeal:

Please refer to your supplemental new drug application dated January 12, 2006, received January 13, 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.

This "Changes Being Effected" supplemental new drug application provides for an updated patient package insert in response to comments from the Office of Drug Safety.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 12, 2006.

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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