DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-835/S-018

Procter & Gamble Pharmaceuticals, Inc.
Attention: Katherine McNeil
U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. McNeil:

Please refer to your supplemental new drug applications (NDA) dated November 11, 2004, received November 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the addition of adverse events reported during the post-marketing experience that are related to hypersensitivity and skin reactions, an additional revision to the pregnancy precaution, and proposes changes to the patient package insert to reflect the changes being made to the package insert.

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 November 11, 2004.

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) 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/

David Orloff

5/6/05 03:24:39 PM