



NDA 20-835/S-028

Procter & Gamble Pharmaceuticals, Inc.
Attention: Maria Petrey
U.S. Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. Petrey:

Please refer to your supplemental new drug application dated May 4, 2007, received May 7, 2007, 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 30 mg to the parenthetical phrase following lactose monohydrate in the Inactive Ingredients sections of both the package insert (PI) and patient information leaflet (PIL).

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 4, 2007.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

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: Package Insert and Patient Information Leaflet

**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
7/24/2007 03:38:08 PM