



NDA 20-835/S-025

Procter & Gamble Pharmaceuticals, Inc.  
Attention: Gary Galletta, Pharm.D.  
Associate Director, U.S. Regulatory Affairs  
Mason Business Center  
8700 Mason-Montgomery Road  
Mason, OH 45040-9462

Dear Dr. Galletta:

Please refer to your supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated June 15, 2006 and received June 16, 2006 for Actonel (risedronate sodium) Tablets.

We acknowledge receipt of your submissions dated September 13, October 12, and 26, 2006, and February 2, and 12, March 13, 14, 16, 21, 22, 23, 26, and 28, and April 4, 5, and 12, 2007

This supplemental new drug application provides for the use of Actonel 75 mg two consecutive days per month for the prevention and treatment of postmenopausal osteoporosis.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert submitted April 12, 2007, and carton labels submitted April 4, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. For administrative purposes, designate this submission “**FPL for approved NDA 20-835/S-025.**” Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Eric Colman  
4/16/2007 12:17:25 PM  
Eric Colman for Mary Parks