



NDA 20-835/S-008, S-009

Procter & Gamble Pharmaceuticals
Attention: Gary Galletta, Pharm.D.
U.S. Regulatory Affairs Manager
Health Care Research Center
8700 Mason Montgomery Road, SB4-3E5
Mason, OH 45040-9562

Dear Dr. Galletta:

Please refer to your supplemental new drug applications dated July 23, 2001, received July 25, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) 35 mg Tablets.

We acknowledge receipt of your submissions dated July 23, September 4, September 19, November 1, December 4, 2001, and January 24 and 31, February 19 and 21, March 15 and 25, April 1, 11, 12, 17(2), 18, 24, 29, and 30, and May 2, 8, 9, 10, 13, and 14, 2002.

These supplemental new drug applications provide for once-a-week dosing of Actonel (risedronate sodium) 35 mg Tablets for the treatment (S-008) and prevention (S-009) of postmenopausal osteoporosis.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 10, 2002, patient package insert submitted May 14, 2002, immediate container and carton labels submitted February 21, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 20-835/S-008, S-009." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated April 18, 2002:

The commitment is to conduct a one-year, placebo-controlled study of risedronate 35 mg once-weekly in women who are between 6 and 60 months postmenopausal, and who have a T-score > -2.5. The primary endpoint is percent change in lumbar spine bone mineral density.

Protocol Submission:	The protocol was submitted on April 18, 2002
Study Start:	Within six months of the date of this letter
Final Report Submission:	Within three years of the date of this letter

Submit clinical protocols to your IND for this product and all study final reports to these supplemental NDAs. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to the NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol Amendment**," "**Postmarketing Study Final Report**," or "**Postmarketing Study Correspondence**."

Sufficient stability data has been submitted to support a(b)-month expiration date.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We note that in our letter dated April 14, 2000 to you concerning NDA 20-835 we waived requirements of 21 CFR 314.55 (or 601.27) for the indications of prevention and treatment of postmenopausal osteoporosis.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

**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

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