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APPLICATION NUMBER: 20-835/S001-004

APPROVAL LETTER

NDA 20-835/S-001, S-002, S-003, S-004

Procter and Gamble Pharmaceuticals
Attention: Linda Manning, Pharm. D.
Senior Scientist, Regulatory Affairs
11450 Grooms Road
Cincinnati, OH 45242-1434

Dear Dr. Manning:

Please refer to your supplemental new drug applications dated December 18, 1998 and received December 18, 1998 (S-001, S-002, and S-003), and August 27, 1999, received August 30, 1999 (S-004), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) Tablets.

We acknowledge receipt of your submissions dated January 11 and 28, February 3, 8, 9, 10, 15, 25, and 26, March, 1, 3, 5, 8, 12, 22, 26, 29, 30, and 31, April 5(2), 12, 13, 20, and 22, May 7, 13, and 17, June 1, 10(2), 17, 18, 24, and 30, July 1, 2, 12(2), 13, 14, 28, and 30, August 3(2), 20, 27, and 30, September 3, 21, 22, 28, and 29, October 8, 22(2), and 29, November 2 and 9, and December 2, 10, 17, 22, and 29, 1999, and January 12, 14, and 24, February 3 and 28(2), March 1, 2(2), 3, 6(3), 9(3), 13, 16, 21, 22, 24, 29(2), and April 4 and 11, 2000. Your submission of August 27, 1999, constituted a complete response to our August 20, 1999, action letter (S-001) and your submission of December 29, 1999 constituted a complete response to our October 18, 1999 action letter (S-001, S-002, S-003 and S-004).

These supplements propose the following changes:

1. Supplement 001 provides for a new indication for the treatment of corticosteroid-induced osteoporosis.
2. Supplement 002 provides for a new indication for the prevention of postmenopausal osteoporosis.
3. Supplement 003 provides for a new indication for the treatment of postmenopausal osteoporosis.

4. Supplement 004 provides for a new indication for the prevention of corticosteroid-induced osteoporosis.
5. All four supplements provide for a new 5 mg strength tablet.

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 April 11, 2000, patient package insert submitted April 11, 2000, immediate container and carton labels submitted December 18, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-835/S-001, S-002, S-003, S-004." Approval of these submissions by FDA is not required before the labeling is used.

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 are waiving the pediatric study requirement for this action on this application. 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-40
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 Practitioner" 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

Please submit one market package of the drug product when it is available.

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, contact Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

**APPEARS THIS WAY
ON ORIGINAL**