



NDA 020835/S-036

**SUPPLEMENT APPROVAL**

Procter & Gamble Pharmaceuticals, Inc.  
Attention: Gary F. Galletta, PharmD  
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 dated and received May 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ACTONEL® (risedronate sodium) tablets.

We acknowledge receipt of your submissions dated July 17, 2009, and November 11, 2009.

This supplemental new drug application provides for class labeling changes to the CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS Sections of the HIGHLIGHTS AND FULL PRESCRIBING INFORMATION of Physician Labeling. These changes (1) contraindicate the use of ACTONEL in patients with abnormalities of the esophagus which delay emptying and (2) provide additional information regarding upper gastrointestinal adverse events associated with the use of bisphosphonates.

Patient labeling (section entitled “Who should not take ACTONEL”) also was updated to reflect the changes in Physician Labeling.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed package insert and patient package insert labeling. For administrative purposes, please designate this submission, “**SPL for approved NDA 020835/S-036.**”

**PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter,

submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

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

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

*{See appended electronic signature page}*

Scott Monroe, M.D.  
Director  
Division of Reproductive and Urologic Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20835	SUPPL-36	PROCTER AND GAMBLE PHARMACEUTICALS INC PROCTER AND GAMBLE CO	ACTONEL (RISEDRONATE SODIUM) 30MG TABS

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SCOTT E MONROE  
12/31/2009