DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-835/S-035 **APPROVAL LETTER**

P&G Pharmaceuticals, Inc.
Attention: Thomas P. Demuth, Ph.D.
U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040

Dear Dr. Demuth:

Please refer to your supplemental new drug application (sNDA) submitted and received on January 26, 2009, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel® (risedronate sodium) tablets.

We also acknowledge receipt of your amendments dated April 3, 8 and 17, May 21, June 10, and July 17, 2009.

This supplemental new drug application provides for labeling revisions to the **USE IN SPECIFIC POPULATIONS** section, **Pediatric Use** subsection of the Actonel® Package Insert. The revisions were based on the results of your pediatric studies conducted in response to the Pediatric Written Request issued on April 19, 2002.

Additional revisions of the Package Insert include changes to the following sections: (1) **WARNINGS AND PRECAUTIONS**, **Jaw Osteonecrosis** subsection; (2) **USE IN SPECIFIC POPULATIONS**, **Pregnancy**, **Renal Impairment**, and **Hepatic Impairment** subsections, and (3) **NONCLINICAL TOXICOLOGY**.

We have completed our review of this application and 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(1)] in structured product labeling (SPL) format as described at Http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-835/S-035."

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable. We determined that PREA does not apply to your application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 insert 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

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-0881.

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

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

/s/

Scott Monroe

7/23/2009 12:43:02 PM