DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017831/S-055 **SUPPLEMENT APPROVAL**

Procter & Gamble Pharmaceuticals, Inc.
Attention: Thomas Demuth, Jr., Ph.D.
U.S. Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9760

Dear Dr. Demuth:

Please refer to your supplemental new drug application dated May 29, 2009, and received June 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Didronel® (etidronate disodium) tablets.

We acknowledge receipt of your submission dated November 20, 2009.

This supplemental new drug application provides for class labeling changes to the CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS Sections of the Package Insert. These labeling changes:

1. Contraindicate the use of Didronel in patients with abnormalities of the esophagus that delay emptying.
2. Provide additional information regarding upper gastrointestinal adverse events associated with the use of bisphosphonates in the WARNINGS Section.
3. Provide additional information regarding osteonecrosis of the jaw (ONJ) in the PRECAUTIONS Section.

Other changes in the Package Insert include:

1. Revision of the DOSAGE AND ADMINISTRATION Section.
2. Revision of the DESCRIPTION and HOW SUPPLIED Sections to remove the 200 mg tablet as an available dosage form.

We have completed our review of this application, as amended. 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 labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 017831/S-055**."

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-17831	SUPPL-55	PROCTER AND GAMBLE PHARMACEUTICALS INC SUB PROCTER AND GAMBLE CO	DIDRONEL

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

/s/

SCOTT E MONROE
12/31/2009