DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-831/S-054

Procter & Gamble Pharmaceuticals, Inc.
Attention: Katherine McNeil
U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. McNeil:

Please refer to your supplemental new drug applications (NDA) dated July 22, 2005, received July 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Didronel (etidronate disodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for adding information regarding severe musculoskeletal pain, and osteonecrosis of the jaw to the **General** subsection of the **PRECAUTIONS** section, updating the class labeling in the **Pregnancy** subsection of the **PRECAUTIONS** section, and revising the storage condition statement of the package insert to comply with FDA Draft Guidance for Industry entitled, Stability Testing of Drug Substances and Drug Products.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 22, 2005.

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) 796-1224.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Director
Division of Metabolic and Endocrine Products
Office of Drug Evaluation II
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/

Mary Parks

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