DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-762/S-001

Merck & Co., Inc.
Attention: Georgianna Harris, Ph.D.
Director, Regulatory Affairs
P.O. Box 2000, Mail Drop: RY 32-605
Rahway, NJ 07065

Dear Dr. Harris:

Please refer to your supplemental new drug application (NDA) dated July 15, 2005, received July 18, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax Plus D (alendronate sodium 70 mg/2800 I.U. Vitamin D_3) Tablets.

We also refer to your correspondence dated September 19, 2005, containing final printed labeling.

This supplemental NDA provides for a paragraph on osteonecrosis of the jaw to the "**PRECAUTIONS"** section of the package insert, amends the *Post-Marketing Experience* subsection of the **ADVERSE REACTIONS** section of the package insert, and updates the "**What are the possible side effects of FOSAMAX PLUS D?"** section of the patient package insert to reflect the changes in the "**PRECAUTIONS"** section of the package insert.

We have completed our review of this supplemental application as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 19, 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) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
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/

David Orloff

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