DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-040

Merck & Co., Inc.
Attention: Michele Flicker, M.D., Ph.D.
Director, Regulatory Affairs
P.O. Box 2000,
Mail Drop: RY 33-720
Rahway, NJ 07065

Dear Dr. Flicker:

Please refer to your supplemental new drug application dated June 11, 2003, received June 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets.

This supplemental new drug application proposes updating the PRECAUTIONS, *General* section of the Fosamax package insert to emphasize the importance of monitoring serum calcium levels as well as the symptoms of hypocalcemia, modifies the ADVERSE REACTIONS, *Post-Marketing experience, Body as a Whole* section to reflect rare post-marketing adverse event reports of symptomatic hypocalcemia, modifies the ADVERSE REACTIONS, *Post-Marketing Experience, Skin* section to reflect rare reports of severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, and other minor editorial changes.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (text for the package insert and patient package insert) dated June 11, 2003. Accordingly, the supplemental application is approved effective on the date of this letter.

Please note that the attached package insert and patient package insert contains the changes in NDA 21-575, Fosamax (alendronate sodium) Oral Solution. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Drug 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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