DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-030
NDA 21-575/S-002

Merck & Co., Inc.
Attention: Michele Flicker, M.D., Ph.D.
Director, Regulatory Affairs
P.O. Box 2000,
Mail Drop: RY 33-200
Rahway, NJ 07065

Dear Dr. Flicker:

Please refer to your supplemental new drug application (NDA) dated March 22, 2001, received March 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets (NDA 20-560), and your supplemental NDA dated October 31, 2003, received November 3, 2003, also submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Oral Solution (NDA 21-575).

We acknowledge receipt of your submission dated October 31, 2003 to NDA 20-560 which constituted a complete response to our August 4, 2003 action letter for NDA 20-560.

These supplemental new drug applications propose reformatted patient package inserts (PPI) for daily and weekly dosing of Fosamax Tablets and Oral Solution using the Medication Guide format published in the Federal Register on December 1, 1998.

We have completed the review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package inserts submitted October 31, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 20-560/S-030 and NDA 21-575/S-002." Approval of these submissions by FDA is not required before the labeling is used.

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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