DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-038
NDA 21-575/S-007

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 applications (NDA) dated November 2, 2004, received November 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets (NDA 20-560/S-038), and dated October 29, 2004, received November 1, 2004, for the Oral Solution (NDA 21-575/S-007) formulation.

We also refer to your submissions dated November 2, 2004, and November 15, 2005 to NDA 20-560. The November 2, 2004 submission constituted a complete response to our July 23, 2003 action letter.

Further, we refer to your submission dated November 15, 2005 to NDA 21-575.

These supplemental new drug applications provide for information in the **Clinical Pharmacology** and **ADVERSE REACTIONS** sections concerning an osteogenesis imperfecta study, and update the **Precautions** section with the statement that FOSAMAX is not indicated for use in children.

We have completed our review of these supplemental applications, as amended. They 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 text for the submitted labeling (package insert and patient package inserts) submitted November 15, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "FPL for approved supplements NDA 20-560/S-038 and NDA 21-575/S-007." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

12/21/2005 12:30:17 PM