DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-041
NDA 21-575/S-004

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 June 18, 2003, received June 19, 2003, 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 April 9, 2004, received April 12, 2004, 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 April 9, 2004 to NDA 20-560.

These supplemental new drug applications propose new once-weekly dosing in men text for the package insert. The sections of the label that are modified are the CLINICAL PHARMACOLOGY, *men* section, the DOSAGE AND ADMINISTRATION section, the CLINICAL PHARMACOLOGY, *Osteoporosis in men* section, and the ADVERSE REACTIONS, *men* section of the package insert.

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 package insert submitted April 9, 2004).

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-041 and NDA 21-575/S-004." 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

4/16/04 03:20:00 PM