DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-043 & S-044
NDA 21-575/S-005 & S-006

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

Dear Dr. Spaltro:

Please refer to your supplemental new drug applications (NDA) dated May 28, 2004, received June 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets (NDA 20-560/S-043) and Oral Solution (NDA 21-575/S-005).

We acknowledge receipt of your submissions dated July 15, and November 9, 2004.

These supplemental NDAs provide information on bone, joint, and/or muscle pain to be added to the **PRECAUTIONS** section and the *Post-Marketing Experience* subsection of the **ADVERSE REACTIONS** sections of the package insert, and the **What are the possible side effects of FOSAMAX?** section of the patient package inserts.

We also refer to your supplemental NDAs dated September 28, 2004, received October 5, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets (NDA 20-560/S-044) and Oral Solution (NDA 21-575/S-006).

These "Changes Being Effected" supplemental NDAs provide for adding the term "episcleritis" to the *Post-Marketing Experience* subsection of the **ADVERSE REACTIONS** section of the package insert.

We have completed the review of these applications, as amended. 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 and patient package inserts submitted November 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-042 & S-044 and NDA 21-575/S-005 & S-006." 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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