DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-762/S-004

Merck & Co., Inc.
Attention: Frank Seebach, M.D., R.A.C.
Director, Regulatory Affairs
P.O. Box 2000, Mail Drop: RY33-204
Rahway, NJ 07065

Dear Dr. Seebach:

Please refer to your supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated June 23, 2006, and received June 26, 2006, for Fosamax Plus D (alendronate sodium/vitamin D_3) Tablets.

We acknowledge receipt of your submissions dated October 30, and December 20, 2006, and January 11, and 26, and April 6 (2), and 25, 2007.

This supplemental new drug application provides for a combination tablet of 70 mg alendronate (equivalent to 91.37 mg alendronate sodium) and 5600 IU of vitamin D_3 for the treatment of osteoporosis in postmenopausal women and the treatment to increase bone mass in men with osteoporosis.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert submitted April 25, 2007, and carton labels submitted June 23, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an approved new drug.

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. For administrative purposes, designate this submission "**FPL for approved NDA 21-762/S-004**." Approval of this submission 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 are waiving the pediatric study requirements for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (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}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert, Patient Package Insert, Carton Labels

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/s/

Mary Parks

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