NDA 20-560/S-023

September 29, 2000

Merck & Co., Inc.
Attention: Michele R. Flicker, M.D, Ph.D, FACP
Director, Regulatory Affairs
P.O. Box 2000, RY 33-720,
Rahway, NJ 07065

Dear Dr. Flicker:

Please refer to your supplemental new drug application dated March 31, 2000, received March 31, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax® (alendronate sodium) 10mg Tablets.

We acknowledge receipt of your submissions dated June 20, 23, 26, and 28, July 12, 19(2), 26, and 27(2), August 17, 18, and 25, and September 1, 6, 8, 13, 14, 19(2), 20, and 28(2), 2000.

This supplemental new drug application provides for the use of Fosamax for the treatment to increase bone mass in men with osteoporosis.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and patient package insert submitted September 28, 2000).

Please 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 ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-560/S-023." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR

314.55. We are deferring submission of your pediatric studies until December 31, 2002.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Su Yang, MSN, RN, Regulatory Project Manager, at (301) 827-6385.

Sincerely,

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