CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020560/S013

Trade Name: FOSAMAX 5, 10 AND 40 MG TABLETS

Generic Name: ALEDRONATE SODIUM

Sponsor: MERCK RESEARCH LABORATORIES

Approval Date: 6/8/99

INDICATION(s): TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS

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APPLICATION: 020560/S013

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Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)				X
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Pharmacology Review(s)				X
Statistical Review(s)	X			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
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Application Number: 020560/S013

APPROVAL LETTER

NDA 20-560/S-013

JUN - 8 1999

Merck Research Laboratories
Attention: Ms. Michelle Flicker
Director Regulatory Affairs
Sumneytown Pike P.O. Box 4
BLA-20
West Point, PA 19486

Dear Dr. Flicker:

Please refer to your supplemental new drug application dated June 5, 1998, received June 8, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (aledronate sodium) 5, 10 and 40 mg Tablets.

We acknowledge receipt of your submissions dated August 10, 1998, and May 26 and June 4, 1999.

This supplemental new drug application provides for the extension of the use of Fosamax from three to five years for the treatment of postmenopausal osteoporosis. Information from the open label extension studies amends the following sections of the package insert: CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION.

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 draft labeling submitted June 4, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted June 4, 1999.

Please submit 20 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-560/S-013." Approval of this submission by FDA is not required before the labeling is used.

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

Division of Drug Marketing, Advertising, and Communications, HFD-40
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, contact Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

/S/ [redacted] 6/7/99

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research