DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

APR 14 1997

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37B-113
West Point, Pennsylvania 19486

Re: **NDA 20-560**
Fosamax (alendronate sodium tablets)
MACMIS ID #4775

Dear Ms. Westrick:

This letter is in reference to Merck & Co. Inc.'s (Merck) October 18, 1996, FDA Form 2253 submission for Fosamax of a "Compare the Facts" Flashcard (#L7026-996).

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this flashcard and finds that it is misleading and in violation of the Federal Food, Drug, and Cosmetic Act. Specifically, DDMAC objects to the following:

Risk Information

The flashcard is misleading because it fails to present important risk information for Fosamax and thus lacks fair balance. For example, the flashcard fails to present the following risk information:

. Warning regarding reports of serious esophageal adverse experiences reported in patients receiving Fosamax and the need to discontinue therapy if symptoms develop.

. Warning regarding important dosing and administration restrictions required for Fosamax therapy.

Further, the contraindications and risk information presented in the footnote on the reverse side of the flashcard lack prominence in relation to the efficacy information.

Superior Efficacy Claims

The flashcard includes a chart comparing selected points in the prescribing information for Fosamax and Miacalcin. The statements "Demonstrated significant reductions in vertebral fracture risk" and "Built bone in the hip as well as spine over three years" are misleading because they imply superior efficacy of Fosamax versus Miacalcin in the absence of substantial evidence; i.e., data from adequate and well-controlled, comparative trials.

Compliance Claims

The claims of superior compliance for Fosamax versus Miacalcin discussed in the flashcard are misleading because the analysis is based on an assumption of 14 days of therapy per 2 ml container. However, Miacalcin vials actually contain an average of 18 doses. The product labeling reference to 14 doses/vial is the minimum number of doses contained in any vial. Thus, Merck's analysis understates the proportion of patients that fill their Miacalcin prescriptions on time.

DDMAC requests that Merck immediately discontinue the dissemination and use of these materials and other promotional materials that contain similar themes. DDMAC further requests that Merck submit a written response to this letter no later than April 28, 1997, outlining Merck's plan to comply with DDMAC's request.

If Merck has any comments or questions, please contact the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence related to this matter, please refer to MACMIS ID #4775 and the NDA number.

Sincerely,

Anne M. Reb, MS, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

Comments: Lechter 12/12/96
Comments: Burke 12/12/96
Draft: Reb 12/18/96
Revised: Reb 12/24/96
Comments: Feather 12/31/96
Revised: Reb 12/31/96
Comments: Burke 12/31/96
Revised: Reb 1/2/97
Comments: Palmer 1/8/97
Comments: Palmer/O'Brien 1/10/97

Revised: Reb 1/13/97
Comments: O'Brien 2/3/97
Revised: Reb 3/28/97
Comment: Palmer 3/31/97
Comments/Concur: Palmer 4/9/97

CC:
HFD 40/NDA 20-560
HFD 40/Count/Palmer/Reb
HFD 510/NDA 20-560
HFD 510/Dutta/Hedin

MACMIS File ID #: 4775
Macmis type: LETT
Action code: VIOL
fOI: Releasable

Material ID # 45353
L7026-996

fos1010.cha