



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

0818 '03 FEB 28 10:25

Michele R. Flicker, M.D., Ph.D., FACP
Director, Regulatory Affairs
Merck & Co., Inc.
P. O. Box 2000
Rahway, NJ 07065-0900

Re: Docket No. 02P-0363/CP1

Dear Dr. Flicker:

This letter responds to your citizen petition dated August 12, 2002, concerning Fosamax (alendronate sodium) tablets. Your petition requests that FDA include in the administrative record of Docket No. 99P-2547/CP1 the documents described below so that docket will reflect the Agency's current position about the appropriateness and the safety of studying Fosamax in the pediatric population.

- FDA's June 14, 2000, minutes of meeting between the Division of Metabolic and Endocrine Drug Products and Merck in which the Division articulated its position on the use of alendronate in pediatric patients with bone disease.
- FDA's October 27, 2000, written request to Merck for studies of alendronate in pediatric patients with osteogenesis imperfecta.

The Agency has filed those two documents in Docket No. 99P-2547/CP1. Accordingly, your petition is granted.

Sincerely yours,

Janet Woodcock for JW
Janet Woodcock, M.D.

Director
Center for Drug Evaluation and Research

Enclosures

02P-0363

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