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May 22, 2003

MERCK
Research Laboratories

Dockets Management Branch
HFA-305, Room 1061
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

NDA 20-560: FOSAMAX® (Alendronate Sodium Tablets)

Citizen Petition: Administrative Record Update:
Dockets No. 02P-0363/CP1 and 99P-2547/CP1

On February 26, 2003, FDA granted Merck's August 12, 2002 Citizen Petition to update the administrative record of Docket No. 99P-2547/CP1 to reflect the Agency's current position about the appropriateness and safety of studying FOSAMAX® in the pediatric population. Merck is grateful to the Agency for its cooperation in amending this important public record. However, in amending the record, FDA included in the docket copies of both the original October 27, 2000 Written Request for pediatric studies and of the March 8, 2002 amendment to that document.

Since the implementation of Section 505A of the Food, Drug, and Cosmetic Act, FDA has appropriately treated the content of pediatric Written Requests as confidential commercial information and not publically disclosed these documents. FDA has, instead, made public only the fact of the issuance of Written Requests for pediatric studies by listing on its web site products for which such requests have been issued. Merck agrees with the FDA position and thus considers the contents of the October 27, 2000 Written Request and its March 8, 2002 amendment to be confidential and not subject to public disclosure under the Freedom of Information Act without our written permission.

The objective of our Citizen Petition was to correct an otherwise misleading public record of the FDA's conclusion regarding the safety of pediatric studies of alendronate in children. We believe this objective is accomplished effectively by a simple acknowledgment of the issuance of a request for studies. We thus respectfully request the removal of both the

02P-0363

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October 27, 2000 Written Request and its March 8, 2002 amendment from Dockets No. 02P-0363/CP1* and No. 99P-2547/CP1.

*(url: http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/022803/022803.htm#_Toc36438876)

Sincerely yours,

Michele R. Flicker, MD, PhD, FACP
Director,
Regulatory Affairs

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Q:king/fosamax/nda/citizen petition May 2003