



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 6 2000

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Dr. Michele R. Flicker
Director, Regulatory Affairs
Merck & Co., Inc.
West Point, Pa. 19486

Re: Docket Nos. 99P-2547/CP1 and 98N-0056

Dear Dr. Flicker:

This letter responds to your citizen petition dated July 28, 1999, requesting that the Food and Drug Administration (FDA) add alendronate sodium to the priority section of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and determined that it will not add alendronate sodium to the priority section of the list.

Although alendronate sodium is approved for glucocorticoid osteoporosis, an indication for which additional therapeutic options for the pediatric population are needed, we do not believe it is appropriate to study alendronate sodium in pediatric populations. Alendronate therapy in the pediatric population poses substantial long-term safety concerns regarding bone growth, fracture healing, structural integrity, and osteoblast recovery following steroid withdrawal. In general, given the safety concerns associated with many resorptive agents, including alendronate sodium, it may be wisest to treat children supportively, in anticipation of bone recovery following steroid withdrawal.

Accordingly, your petition is denied.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

98N-0056

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