



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

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Kathleen M. Sanzo, Esq.  
Lawrence S. Ganslaw, Esq.  
Morgan, Lewis & Bockius, LLP  
1800 M Street, N.W.  
Washington, DC 20036

Re: Docket No. 01P-0323/CP1

Dear Ms. Sanzo and Mr. Ganslaw:

I am writing to inform you that the Food and Drug Administration (FDA) is still considering the issues raised in your citizen petition submitted on July 30, 2001, on behalf of of Pfizer Inc and Pharmacia Corporation. Your petition requests that FDA revise its policies regarding approval of application submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act and assignment of therapeutic equivalence evaluation codes.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. Because of their complexity, we are still considering the issues raised in the petition. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

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

01P-0323

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