DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 16 2003

Kathleen M. Sanzo, Esq.
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Docket No. 02P-0447/CP1

Dear Ms. Sanzo:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on October 11, 2002, on behalf of Pfizer Inc. Your petition requests, among other things, that the Agency immediately revoke its acceptance for filing and receipt of New Drug Application (NDA) 21-435 for amlodipine maleate tablets.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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

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