



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 22 2001

9 4 9 4 '01 JUN 28 09:20

Salvatore J. Graziano
Milberg, Weiss, Bershad, Hynes, and Lerach LLP
One Pennsylvania Plaza
New York, NY 10119-0165

Re: Docket No. 01P-0010/CP1

Dear Mr. Graziano:

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 January 4, 2001, on behalf of Lawrence D. Bernhardt and Arnold Liebman. Your petition requests that the Agency take certain actions regarding Pfizer Inc.'s anti-hypertension drug, Cardura, in light of the findings of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) conducted by the National Heart, Lung, and Blood Institute.

FDA has been unable to reach a decision on your petition because it raises significant/complex issues requiring extensive review and analysis by Agency officials and because of the scheduling of the Cardio-Renal Advisory Committee meeting. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your request as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

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

01P-0010

LET 1