



Food and Drug Administration
Rockville MD 20857

FEB 12 2003

James Feldman, M.D. FACEP
Department of Emergency Medicine
Boston Medical Center
818 Harrison Avenue
Boston, Massachusetts 02118

Re: Docket No. 02P-0374/CP1

Dear Dr. Feldman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition received on August 15, 2002, requesting that a Black Box warning be added to the labeling of angiotensin converting enzyme inhibitors (ACE inhibitors).

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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

02P-0374

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