



Food and Drug Administration
Rockville MD 20857

SEP 1 2004

Sidney M. Wolfe, M.D.
Director
Public Citizen Health Research Group
1600 20th Street, N.W.
Suite 750
Washington, D.C. 20009-1001

Docket Number: 2004P-0113/CP1

Dear Dr. Wolfe:

This letter responds to your citizen petition dated March 4, 2004, requesting that the Food and Drug Administration (FDA or the Agency) immediately remove from the market rosuvastatin (Crestor), marketed by AstraZeneca.

I am writing to inform you that we have not yet resolved the issues raised in your petition because it identifies significant matters 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,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0113

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