DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 1 2007

Anil K. Mandal, M.D.
240 Southpark Circle East
St Augustine, Florida 32086

Re: Docket No. 2006P-0351/CP1

Dear Dr. Mandal:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 6, 2006. Your petition requests that FDA restrict the use of or withdraw from the market angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) therapy in certain conditions because of an association with acute renal failure.

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,

Jane A. Axelrad

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

2006P-0351

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