



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

OCT 27 2006

3462 6 OCT 31 2006

Sidney Wolfe, MD
Joseph Baker, MD, MPH
Peter Lurie, MD, MPH
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. 2006P-0178/CP1

Dear Drs. Wolfe, Baker, and Lurie:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on May 1, 2006. Your petition requests that the Agency immediately ban the fluoroquinolone antibiotic gatifloxacin because of the increased risk of dysglycemia in humans.

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
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0178

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