HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 26 2007

Jay Parkinson, MD, MPH
Sidney M. Wolfe, MD
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. 2006P-0371

Dear Drs. Parkinson and Wolfe:

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 August 29, 2006. Your petition requests that the Agency add a black box warning regarding the risks of tendinopathy and tendon rupture to the product labels of all fluoroquinolone antibiotics presently on the market in the United States. You also request that FDA mandate a "Dear Doctor" letter to warn physicians of the adverse effects associated with these drug products and require the distribution of a Medication Guide.

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

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