DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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November 16, 2005

Arnold L. Widen, MD, MS, FACP
Babs Waldman, MD
Office of the Attorney General
State of Illinois
100 W. Randolph Street
Chicago, IL 60601

Re: Docket No. 2005P-0205

Dear Drs. Widen and Waldman:

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 24, 2005. Your petition requests that the Agency take the following actions with respect to the entire class of fluoroquinolone drug products and the potential adverse event of tendonopathy and tendon rupture to: 1) revise the labeling to increase the warnings, 2) provide "Black Box" warnings, 3) require manufacturers to issue a "Dear Health Care Professional" letter that informs these professionals of the potential health hazards associated with the use of this class of drugs and details your proposed labeling changes, 4) supplement information provided to patients with bolded warnings, and 5) submit the issue for review and analysis to FDA's Drug Safety Oversight Board.

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

2005P-0205

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