



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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

**FILE COPY**

Dear Drs. Parkinson and Wolfe:

Your petition requesting the Food and Drug Administration to immediately 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, was received by this office on 08/29/2006. It was assigned docket number 2006P-0371/CP1 and it was filed on 09/08/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0371

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