



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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