



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 18 2006

Elizabeth Barbehenn, Ph.D.
Peter Lurie, M.D.
Sidney M. Wolfe, M.D.
Howard D. Pomeranz, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Re: Docket No. 2005P-0423/CP1

Dear Drs. Barbehenn, Lurie, Wolfe, and Pomeranz:

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 October 20, 2005. Your petition requests that the Agency immediately add a black box warning regarding the risks of drug-induced blindness to the labeling for the three phosphodiesterase 5 (PDE5) inhibitors that are prescribed for the treatment of erectile dysfunction, and for Revatio, a version of sildenafil indicated for pulmonary arterial hypertension. You also request that FDA require the distribution of Dear Doctor letters and Medication Guides, and the establishment of a registry of patients diagnosed with non-arteritic ischemic optic neuropathy (NAION).

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

2005P-0423

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