DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Alessandra C. Ravetti
Emily Marden
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

2548 APR 23 2007 APR 26 A10 :09

Re: Docket No. 2006P-0450/CP 1

Dear Ms. Ravetti and Ms. Marden:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 2, 2006. Your petition requests that FDA (1) revoke approval of Allergan, Inc.'s supplemental new drug application (sNDA) 21-275/S-013 for Lumigan (bimatoprost ophthalmic solution 0.03%) for a first-line indication and (2) deny approval of Alcon, Inc.'s sNDA 21-257 for Travatan (travoprost ophthalmic solution 0.004%) for a first-line indication.

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

2006P-0450

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