



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 26, 2006

FILE COPY

Jeffrey Chasnow
Emily Marden
Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Chasnow and Ms. Marden:

Your petition requesting the Food and Drug Administration to take appropriate remedial action against the apparent misbranding of generic azithromycin marketed by Pliva, Inc. and to reexamine the Pliva Abbreviated New Drug Application filed for azithromycin, to ensure that it contains accurate and complete information regarding the active ingredient contained in the Pliva product, was received by this office on 05/26/2006. It was assigned docket number 2006P-0224/CP 1 and it was filed on 05/26/2006. 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-0224

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