DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV 20 2006

Food and Drug Administration
Rockville MD 20857

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

Re: Docket No. 2006P-0224/CP1

Dear Mr. Chasnow 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 May 26, 2006. Your petition asserts that certain generic azithromycin tablets marketed by Pliva, Inc. (Pliva) appear to be misbranded because the drug product's label incorrectly identifies the polymorphic form of the active ingredient contained in the tablets. You request that FDA therefore take appropriate remedial action against the alleged misbranding of this product and reexamine Pliva's abbreviated new drug application for azithromycin to ensure its completeness and accuracy with respect to the active ingredient.

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,

Nancy E. Boockes
for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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