DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 1 2006

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

Re: Docket No. 2006P-0070/CP1

Dear Mr. Chasnow:

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 February 9, 2006. Your petition asserts that the generic azithromycin products marketed by Teva Pharmaceuticals USA and Sandoz Inc. appear to be misbranded because their labels incorrectly identify the polymorphic forms of the active ingredient contained in the products. You request that FDA therefore take appropriate remedial action against the alleged misbranding of these products and reexamine their abbreviated new drug applications to ensure their 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,

Jane A. Axelrad

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