DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 25 2011

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

Re: Docket Nos. FDA-2006-P-0079, FDA-2006-P-0273, and FDA-2006-P-0448

Dear Mr. Chasnow and Ms. Marden:

This responds to your citizen petitions dated February 9, 2006, May 25, 2006, and October 4, 2006 (Petitions).[1] The Petitions request that the Food and Drug Administration (FDA or Agency) take the following actions:

- Advise Teva Pharmaceuticals USA (Teva); Sandoz Inc. (Sandoz); and Pliva, Inc. (Pliva) (collectively, the Companies) that their generic azithromycin products are misbranded.
- Reexamine the approved abbreviated new drug applications (ANDAs) and any pending ANDAs for generic azithromycin filed by the Companies to ensure that they contain complete and accurate information (including appropriate stability, dissolution, and bioavailability data) regarding their active ingredient.
- Pursue remedial action (e.g., suspension or withdrawal of ANDA approval) against the Companies for any misbranded generic azithromycin products.
- Initiate a recall of any misbranded generic azithromycin products that the Companies do not voluntarily cease to distribute.

In the Petitions, you contend that the generic azithromycin products marketed by the Companies are misbranded because they are labeled to contain azithromycin in the monohydrate form. You state that Pfizer analyzed market samples of the Companies' azithromycin products and found that they contain primarily azithromycin in the sesquihydrate form (and minimal azithromycin in the monohydrate form). The Petitions

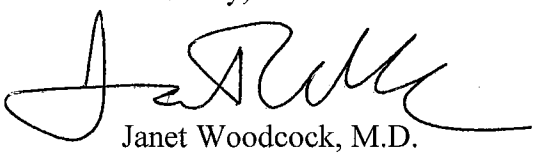
[1] The February 9, 2006; May 25, 2006; and October 4, 2006 citizen petitions were originally assigned docket numbers 2006P-0070/CP1, 2006P-0224/CP1, and 2006P-0406/CP1, respectively. These numbers have been changed to FDA-2006-P-0273, FDA-2006-P-0079, and FDA-2006-P-0448, respectively, as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

further state that differences in polymorphic form may affect drug quality, safety, and efficacy.

The Petitions request that FDA take enforcement action against the Companies for marketing misbranded generic azithromycin products. Decisions with respect to initiating enforcement actions, however, are generally made by the Agency on a case-by-case basis and are within the discretion of the Agency. Requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures (see 21 CFR 10.30(k)). Accordingly, this request is not an appropriate request for a citizen petition. Therefore, the Petitions are denied.

We nevertheless appreciate the information that you provided. Such information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce. We take complaints seriously, and we will evaluate this matter to determine what follow-up action is appropriate.

Sincerely,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research