ARNOLD & PORTER LLP

Donald O. Beers
Donald_Beers@aporter.com

202.942.5012
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

April 20, 2007

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Request for Stay Granting Provisional Market Exclusivity and Patent Listing for Ziana™

Dear Sir or Madam:

PETITION FOR STAY OF ACTION

We submit this Petition for Stay of Action under 21 C.F.R. § 10.35, on behalf of Medicis. We are today submitting a related citizen petition asking FDA to change its policy with respect to market exclusivity and listing of patents for drugs that contain combinations of active ingredients, when one but not all of the active ingredients is an antibiotic ingredient that was part of a product that was included in an application submitted to FDA for review prior to November 21, 1997 (a "pre-1997 antibiotic ingredient").

A. Decision involved

Because it has denied 3-year market exclusivity to Ziana™ and has refused to list the patent information submitted for this drug, FDA may at any time be asked to approve an abbreviated new drug application ("ANDA") or Section 505(b)(2) application that references the Ziana™ new drug application ("NDA"). If FDA should grant the relief requested in the citizen petition submitted on the same date as this petition for stay of action, such an approval would not be appropriate.

B. Action requested

Medicis asks that FDA grant a stay of its decision to deny market exclusivity and patent listing for Ziana™. Specifically, the requested stay would:

1. prevent the approval of any ANDA or Section 505(b)(2) application referencing the Ziana™ NDA during the 3–year of market exclusivity that would be earned by the Ziana™ application if the citizen petition is granted, and

2. provisionally list the patents submitted by Medicis for Ziana™ in the Orange Book.

Medicis requests that the stay continue until resolution of the issues raised by the accompanying citizen petition. Should FDA deny that citizen petition in whole or in part, Medicis asks that the stay requested herein not expire until a reviewing court has ruled on the correctness of that decision, so long as Medicis seeks court review within thirty days of its receipt of the adverse decision.

C. Statement of grounds

Ziana™ was approved on November 7, 2006. The Ziana™ NDA requested 3-year marketing exclusivity pursuant to 21 CFR 314.108(b)(4). We believe that there should be no dispute that, were it not for FDA's conclusion that this drug was ineligible for market exclusivity because it contained a pre-1997 antibiotic ingredient, that exclusivity would have been granted.

On December 7, 2006, Medicis timely filed Forms 3642 for two patents that claim Ziana™. Again, were it not for FDA's conclusion that this drug was ineligible for patent listing because it contained a pre-1997 antibiotic ingredient, it is clear that FDA would be obligated to list these patents in the Orange Book.

The accompanying citizen petition demonstrates FDA's conclusion that Ziana™ was ineligible for exclusivity and patent listing because it contained a pre-1997 antibiotic ingredient is wrong, as a matter of policy and as a matter of governing law. Accordingly, it is crucial that ANDAs or 505(b)(2) applications that refer to Ziana™'s NDA not be approved before FDA has resolved the issues presented by the citizen petition, and if those issues are resolved against Medicis, until Medicis has an opportunity for judicial review of that decision.

There is precedent for granting stays where, as here, significant legal and policy issues have been raised about FDA policies. *See, e.g.*, 45 Fed. Reg. 82,052 (Dec. 12, 1980) (reference to stay of "paper NDA" policy until 10 days after denial of citizen petition challenging that FDA policy).

This petition for stay of action satisfies the prerequisites for a mandatory grant of a stay under FDA regulations. *See* 21 C.F.R. § 10.35(e)(1)-(4).

The petitioner will otherwise suffer irreparable injury. Here, Medicis will lose sales of its Ziana™ products to generic products once they are marketed. There is no mechanism by which the harm to Medicis, if it occurs, can be repaired.

Moreover, there is a risk that the benefit to Medicis of the patent protections to which it is entitled may disappear, even if it prevails in its citizen petition, with respect to any generic application that may be filed before FDA grants that petition. This is because the 30-month delay in approval of the generic while patent litigation proceeds applies only in situations in which the patent information is provided to FDA by the NDA holder before the generic application is submitted. *See* Federal Food, Drug, and Cosmetic Act Section 505(j)(5)(B)(iii), 21 U.S.C. § 355(j)(5)(B)(iii). Medicis would argue, and FDA might well concur, that if FDA grants the petition, the patent information on Ziana™ should be considered to have been submitted at the date it was originally provided to FDA (as opposed to the date when FDA ultimately agrees to accept it). A potential generic applicant could, however, take the opposite position. Because no one can predict with certainty how a court would resolve a dispute on that issue, it is important that FDA list the patents claiming Ziana™ provisionally while it considers the Ziana™ petition.

The petitioner's case is not frivolous and is being pursued in good faith. The accompanying citizen petition illustrates that the petitioner's case is not frivolous and is well grounded in applicable law. This matter is being pursued in good faith, with every attempt being made to seek resolution in an appropriate and expeditious manner based on the application of applicable law to the facts presented.

The petitioner has demonstrated sound public policy grounds supporting the stay. The accompanying citizen petition is, to a significant extent, premised on public policy. If that petition is granted, the policy reasons articulated there will make an intervening approval of a generic product unfair and inappropriate. The issue is clearly a significant one, whose prompt resolution is important to all concerned. A stay until FDA responds to Medicis's citizen petition addressing the questions raised is certainly justified.

The delay resulting from the stay is not outweighed by public health or other public interest. Once the issues presented by the citizen petition are addressed by FDA, petitioner is confident that FDA will conclude that Ziana™ qualifies for both market exclusivity and patent listing. There is no public interest in the marketing of generic products that are not entitled to approval under the law. More generally, there can be no public interest in having FDA rush into inappropriate approvals.

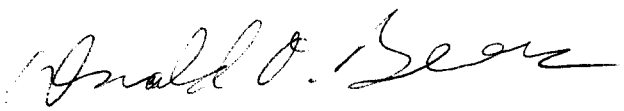
Even were FDA not to find that the criteria for mandatory stay discussed above had been satisfied, such a stay should be granted under the Agency's discretionary authority to stay any action "in the public interest and in the interest of justice." 21 C.F.R. § 10.35(e). The issues raised by Medicis's citizen petition are clearly substantial. The interests of the public and of justice demand a fair and expeditious resolution of those issues in an orderly process, without penalizing Medicis while that process proceeds.

Without either exclusivity or patent listing, Medicis has no way of knowing whether generic applications referencing Ziana™ may have been filed. Accordingly, Medicis asks that the requested stay be entered as soon as possible.

Of particular concern, it is FDA's general practice not to provide substantive responses to citizen petitions within the 180–day period provided for such responses in FDA regulations, and instead to provide an interim response that does not answer the petition substantively. Because 180 days after filing of these petitions will approach one year since the approval of Ziana™, lack of action on the petition by that date will put Medicis in serious jeopardy of facing generic competition for its product at any point. Thus, in the absence of a grant of the citizen petition, or of this petition, within the

180–day period, Medicis currently expects to seek judicial review at the end of that period.[1] It would accordingly avoid inappropriate expenditure of resources by both Medicis and the government if this petition for stay is granted.

Respectfully submitted,



Donald O. Beers
Joshua M. Glasser
ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004-1206
Telephone: 202-942-5012

[1] Should Medicis obtain information that suggests that a generic application will be approved before that date, then it may be required to seek judicial relief earlier, if this stay petition is not granted.