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Via Hand Delivery

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Petition for Stay of Action -- Approval of ANDAs for Clonidine Transdermal Patch Products That Do Not Meet Appropriate Approval Standards
Docket No.: 01P-0470/PSA 1

Dear Sir or Madam:

We represent Mylan Technologies, Inc. ("Mylan"), holder of a pending ANDA for a generic clonidine transdermal product. Pursuant to 37 C.F.R. §10.35, Mylan submits this opposition to the above-referenced Petition for Stay of Action -- Approval of ANDAs for Clonidine Transdermal Patch Products That Do Not Meet Appropriate Approval Standards ("Petition for Stay"), filed by Arnold and Porter on behalf of Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") on October 10, 2001. Mylan has an interest in the outcome of the Petition for Stay because the petitioner has requested, inter alia, that the FDA stay approval of any approved application or decision to approve any new or pending application for generic clonidine transdermal products if the products differ in "identified ways" from Catapres-TTS, until final resolution (including exhaustion of appeals) of the issues raised in BI's Citizen Petition. This requested action, if granted, that could adversely affect approval of Mylan's ANDA.

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In the Petition for Stay, BI asserts that the accompanying Citizen Petition "demonstrates that the marketing of generic clonidine transdermal products with different release mechanisms or inactive ingredients or that do not meet the proposed bioequivalence requirements, would be contrary to law." Petition for Stay at 2. BI also raises public safety issues in support of its Petition. Id. Mylan respectfully submits that the Petition for Stay should be denied because the accompanying Citizen Petition does not, in fact, demonstrate or establish that approval of generic clonidine transdermal products that differ from Catapres-TTS would be contrary to law, or in any way pose a risk to public health and safety. Mylan has filed an opposition to the Citizen Petition simultaneously with the present opposition, in which it explains in detail the deficiencies of the Citizen Petition, and why the actions requested therein should be denied.

Mylan further submits that the present situation is virtually identical to that presented in the Citizen Petition and Petition for Stay of Action filed by Berlex Laboratories and 3M Pharmaceuticals seeking delay in approval of certain ANDAs for generic estradiol transdermal products (Docket No. 98P-0434/CP1 and PSA1) (the "Estradiol Petition"). In the Estradiol Petition, virtually the same public health and safety issues were raised as are raised in the BI Citizen Petition. See March 17, 2000 letter denying the Estradiol Petition, Exhibit A to the Citizen Petition (the "Estradiol Denial"), at 1. The FDA denied the Estradiol Petition, stating that "approval of a generic estradiol transdermal drug delivery system will be based on sound scientific standards applicable to the review of such a product." Estradiol Denial at 25. The FDA stated that (1) because it would not be appropriate to deny the public the benefit of a lower priced generic product in the absence of scientific evidence that a delay in approval of an ANDA is necessary to protect public health, and (2) because the Estradiol Petition does not contain such evidence, it concluded that the Estradiol Petition had neither demonstrated sound public policy grounds for a stay nor shown that public health interests outweighed the delay that would result from imposition of a stay. Estradiol Denial at 25.

Here, as in the Estradiol Petition, the BI Citizen Petition fails to demonstrate sound public policy grounds for a stay, or show that public health interests outweigh the delay resulting from imposition of a stay. Instead, as set out in detail in Mylan's opposition to the Citizen Petition, BI speculates regarding potential harm and provides no evidence that the untoward events outlined as possibilities are in fact likely to happen. See Mylan opposition to Citizen Petition; c.f. Estradiol Denial at 25. As shown in Mylan's opposition to the Citizen Petition, BI has failed to meet the requirements of a mandatory stay under 21 C.F.R. 21 C.F.R. § 10.35(e)(1)-(4), and its Petition for Stay should be denied.

CONCLUSION

For all of the foregoing reasons, the Petition for Stay should be denied.

Respectfully submitted,

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