Pfizer Inc
235 East 42nd Street 235/24/10A
New York, NY 10017-5755
Tel 212 733 5225 Fax 646 383 9498
Email Jeffrey.b.chasnow@pfizer.com

Jeffrey B. Chasnow
Assistant General Counsel
Legal Division

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, M 20857

PETITION FOR STAY OF ACTION

On behalf of Pfizer Inc ("Pfizer"), the undersigned submit this petition requesting that the Food and Drug Administration ("FDA") stay approval of any and all supplements to NDA 20-362, the Novartis Pharmaceuticals Corporation ("Novartis") new drug application ("NDA") for Lotrel® (amlodipine besylate; benazepril hydrochloride), until after Pfizer's pediatric exclusivity for amlodipine has expired on September 25, 2007. Simultaneously with this Petition for Stay of Action, Pfizer is filing a Citizen Petition requesting that FDA: (1) deem the Lotrel® NDA a section 505(b)(2) application subject to the amlodipine pediatric exclusivity; (2) rescind final approval of the Lotrel® NDA; and (3) withhold final approval of any supplemental NDA ("sNDA") submitted by Novartis to its Lotrel® NDA because any such sNDA is a section 505(b)(2) NDA subject to the amlodipine pediatric exclusivity. The basis for this Petition for Stay of Action is set forth below, and in Pfizer's accompanying Citizen Petition, incorporated herein by reference.

A. Decision Involved

This Petition for Stay of Action pertains to any and all sNDAs, including any and all "Changes Being Effected" ("CBE") supplements, filed to NDA 20-362 concerning the amlodipine ingredient in Lotrel®.

B. Action Requested

Pfizer requests that FDA stay approval or the effective date of approval of any and all supplements to the Lotrel® NDA concerning the amlodipine ingredient in Lotrel® until after Pfizer's pediatric exclusivity for amlodipine has expired on September 25, 2007.

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C. Statement of Grounds

The effective date of approval of any sNDAs for Lotrel® concerning the amlodipine ingredient in Lotrel® should be deferred until after September 25, 2007, because Novartis's Lotrel® NDA is subject to Pfizer's pediatric exclusivity. As set forth in the accompanying Citizen Petition, Lotrel® was approved under section 505(b)(1) of the FDCA based on a right of reference to Pfizer's amlodipine IND and NDA. Pfizer granted the right of reference under terms of a License Agreement that Pfizer and Ciba-Geigy Corp., a predecessor to Novartis, executed in 1989.

On March 21, 2007, in response to Novartis's repudiation of the License Agreement, Pfizer notified FDA that Pfizer is revoking Novartis's right of reference to Pfizer's amlodipine IND and NDA, effective midnight, March 25, 2007. (Citizen Petition, Tab 1, Attachment A). As explained in Pfizer's Citizen Petition, as a result of this revocation Novartis's Lotrel® NDA became an application under section 505(b)(2), subject to Pfizer's pediatric exclusivity for amlodipine. Moreover, any supplement to the Lotrel® NDA must also be considered as an NDA under section 505(b)(2) subject to pediatric exclusivity.

Thus, as explained more fully in the Citizen Petition, FDA should defer the effective date of approval of any sNDA for Lotrel® concerning the amlodipine ingredient in Lotrel® until after the expiration of the pediatric exclusivity period for amlodipine. Until now, Pfizer has been supplying amlodipine to Novartis for use in manufacturing Lotrel®. As a consequence of Novartis's repudiation of the License Agreement, however, Pfizer is no longer supplying amlodipine to Novartis. Thus, Pfizer expects that Novartis may seek FDA approval for a manufacturing supplement in order to substitute an alternative amlodipine source.[1] FDA should defer the effective date of any such supplement until after September 25, 2007.

As set forth below, this Petition for Stay of Action satisfies the requirements for a mandatory grant of a stay under agency regulations. 21 CFR § 10.35(e).

The petitioner will otherwise suffer irreparable injury. Pfizer faces imminent, substantial and irreparable injury in the absence of a stay. Pfizer holds the NDA for Norvasc® (amlodipine beyslate), the reference listed drug for amlodipine. In response to a written request from FDA, Pfizer conducted pediatric studies of amlodipine and earned an additional six months of exclusivity as a result. Unless the stay is granted, Novartis will be able to continue selling Lotrel® during the period of pediatric exclusivity. Thus, Pfizer will lose its pediatric exclusivity rights as against Novartis, and, with those rights, the monetary reward to which Pfizer is statutorily entitled after expending substantial efforts on studies of the safety and efficacy of its product in children.

The petitioner's case is not frivolous and is being pursued in good faith. The accompanying Citizen Petition demonstrates that Pfizer's case is not frivolous. Rather, it is strong and compelling, and is being pursued in good faith. Pfizer has raised

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[1] Because Novartis would be seeking approval of a new manufacturing process as well as a new manufacturing site, a prior approval supplement is necessary. 21 CFR 314.70(b); FDA, *Changes to an Approved NDA or ANDA* 3, 9-14 (2004). If Novartis submits a "Changes Being Effected" supplement, FDA should notify Novartis that a prior approval supplement is required.

persuasive legal and policy reasons for enforcing its pediatric exclusivity for amlodipine as against the Lotrel® NDA and for withholding approval of any supplements to that NDA.

The petitioner has demonstrated sound public policy grounds supporting the stay. Pfizer had established sound public policy grounds supporting the stay. As FDA has stated, "[t]he pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date." S. Rep. 107-79 at 5 (2001) (citing FDA's January 2001 Status Report to Congress). The agency has thus repeatedly rejected attempts by generic applicants to manipulate the statutory regime in such a way as to deprive innovators who have invested the extensive time and resources required for pediatric studies of their exclusivity.[2] FDA has been careful to preserve the incentive and to ensure that grants of pediatric exclusivity are certain.

Here, Pfizer responded to the incentive and conducted studies of amlodipine that produced valuable information concerning effects of the drug on children. FDA should not permit Novartis to circumvent Pfizer's pediatric exclusivity and undermine the incentive to conduct pediatric research.

The delay resulting from the stay is not outweighed by public health or other public interests. "The public's interest in 'the faithful application of the laws' outweigh[s] its interest in immediate access to [a competing] product." *Mova Pharma. Corp. v. Shalala,* 140 F.3d 1060, 1066 (DC Cir. 1998). This is particularly true where, as here, the statutory regime provides for a delay in the approval of competing products as an incentive to perform much needed pediatric research and as a reward for those who, like Pfizer, invest in such research. Indeed, as demonstrated above, the public interest is best served by effectuating Pfizer's pediatric exclusivity. Moreover, temporary unavailability of Lotrel® will cause no harm to either the public health or interests. Both amlodipine besylate and benazepril hydrochloride are available as monotherapies. At worst then, the stay could result in a temporary inconvenience.

Even if FDA determines that a mandatory stay is not warranted, a stay should be granted under the agency's discretionary authority. FDA regulations authorize a discretionary stay "in the public interest and in the interest of justice." 21 CFR § 10.35(e). The interests of the public and of justice counsel that Pfizer's pediatric exclusivity should be preserved.

D. Conclusion

For the reasons set forth above and in the attached Citizen Petition, the undersigned request that the Commissioner stay approval of any and all supplements to

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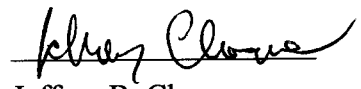
[2] *See e.g., Mylan Labs. v. Thompson,* 389 F.3d 1272 (DC Cir. 2004) (upholding FDA's rejection of Mylan's claim that it was not subject to pediatric exclusivity for fentanyl); *Ranbaxy Labs. Ltd. V. FDA,* Civ. No. 04-5079, 2004 U.S. App. LEXIS 8311 (DC Cir. 2004) (upholding FDA's rejection of Ranbaxy's claim that it was not subject to pediatric exclusivity for fluconazole); *Barr Labs., Inc. v. Thompson,* 238 F. Supp. 2d 236 (DDC 2002) (upholding FDA's rejection of Barr's claim that it was not subject to pediatric exclusivity for tamoxifen).

Novartis's Lotrel® NDA until Pfizer's pediatric exclusivity rights for amlodipine have expired on September 25, 2007.

Respectfully submitted,



Jeffrey B. Chasnow
Kelly A. Falconer
Pfizer Inc
235 E. 42nd Street
New York, NY 10017