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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23 (HFA-305)
12420 Parklawn Drive
Rockville, MD 20857

Subject: Citizen's Petition to FDA Seeking Immediate Approval of ANDA No. 78-226
For Amlodipine Besylate

CITIZEN'S PETITION

The undersigned submits this petition under 21 U.S.C. § 301 *et seq.*, of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 C.F.R. 5.10 to request the Commissioner of Food and Drugs to file papers in opposition to Mylan's application for a temporary restraining order (hereinafter, "TRO") in the case before the United States District Court for the District of Columbia of Mylan Laboratories, Inc. v. Leavitt (Civ. Action No. 07-579), and to move the Court to dissolve the temporary restraining order (hereinafter "TRO") awarded to Mylan Laboratories Inc. *et al* (hereinafter "Mylan") granted by the Honorable Ricardo M. Urbina until April 13, 2007 at 5 pm, in Civil Action No. 07-579. It is further requested that the FDA immediately grant final approvals to all ANDA applicants that have filed a complete amlodipine besylate ANDA.

A. Action requested

This petition is respectfully submitted to request the FDA to file papers in opposition to plaintiff Mylan's application for a TRO in the case of Mylan Laboratories, Inc. v. Leavitt (D.D.C. Civ. Action No. 07-579) and to seek a dissolution of the TRO of the Honorable Ricardo M. Urbina that lasts until April 13, 2007 at 5:00 pm. Additionally, this petition asks the FDA to approve all complete amlodipine besylate ANDA that are currently pending.

2007P-0130

B. Statement of grounds

Petitioner, Zydus Pharmaceuticals USA Inc. (Hereinafter "Zydus"), a Delaware Corporation, produces and sells generic drugs under its approved ANDAs. Zydus has its U.S. corporate headquarters located in Princeton, New Jersey. By this petition, Zydus submits that Mylan's arguments in their application for a TRO seeking an injunction from the court to prevent the FDA from approving complete amlodipine besylate ANDAs is contrary to the law, and without any merit. Zydus hence requests that the FDA file papers in opposition to Mylan's TRO request and to file a motion to dissolve the temporary order issued by the Honorable Ricardo M. Urbina. Zydus respectfully disagrees with the Mylan's request for a TRO for the following reasons:

- a. Zydus believes that Mylan through its petitions and TRO intends solely to prevent any other generic from entering the market during a period in which approved ANDA holders are rightfully permitted to enter the market. Mylan does this to thwart competition so that it can make large profits at the expense of consumers.
- b. Zydus further believes that by obtaining such an order, Mylan intends to extend the 180-day exclusivity period beyond that permitted statutorily in violation of 21 U.S.C. § 355(j)(5)(D)(i)(VI). Zydus believes that Mylan has forfeited any 180-day exclusivity period that may have been awardable to it under the provisions of the Medicare Amendment Act, 2003, codified at 21 U.S.C. § 355.

Extending the duration of the exclusivity beyond the statutory provisions will effectively preclude generic firms such as Zydus from having an opportunity to introduce their generic version of the drug in a fair and timely manner. Such action will clearly be in opposition to the goal of the Hatch-Waxman statutes, that is to bring lower drug prices to the public. It is also contrary to intent of Congress.

Pfizer is the New Drug Application ("NDA") holder of its Norvasc® (amlodipine besylate) tablets under NDA No. 019787. In accordance with the Federal Food, Drug and Cosmetic Act, (21 C.F.R. § 355(b)(1) *et seq.*), Pfizer listed two patents under its NDA listing, *i.e.*, U.S. Patent No. 4,572,909 (hereinafter the '909 Patent), expire on January 31, 2007 and U.S. Patent No. 4,879,303 (hereinafter '303 patent), expiring September 25, 2007 (including pediatric exclusivity). The '909 and '303 patents were originally set to expire on July 31, 2006 and March 25, 2007, respectively.

Mylan was the first to file an Abbreviated New Drug Application, ANDA No. 076418, under which it sought approval to sell generic amlodipine besylate. Mylan certified pursuant to 21 C.F.R. 314.94(a)(12)(i)(A)(4) that it was seeking approval to market its generic copy of Norvasc® prior to the expiration of the '909 and '303 patents. The application stated that to the best of Mylan's knowledge neither the '909 nor the '303 patents would be infringed by the manufacture, use or sale of the proposed generic amlodipine besylate.

Mylan, claiming first to file status, received final approval on October 03, 2005. On November 3, 2005, the court before which it had filed a summary judgment motion of non-infringement, denied all summary judgment motions. Consequently all issues of invalidity and inequitable conduct were tried. On September 15, 2006, Mylan moved to dismiss the '909 patent from the case. On February 27, 2007, the Court issued its ruling, concluding that the '303 patent is valid, enforceable, and infringed and entered judgment for Pfizer.

The '303 patent was, however, invalidated by Apotex, a subsequent ANDA filer, on March 22, 2007 at the Court of Appeals for the Federal Circuit. The Court of Appeals reversed the decision of the Illinois Northern district court concluding that Claims 1-3 of the '303 patent were obvious.

In a press release dated March 23, 2007, Mylan stated that, being the first to file, it had launched its generic version on March 23, 2007 thereby triggering its 180-day exclusivity.

On the 26th of March, 2007, Mylan filed an emergency application for a TRO in the District Court of the District of Columbia seeking an injunction from the court to prevent the Food and Drug Administration (the "FDA") from approving any amlodipine besylate ANDAs already filed by other generics competitors. The Court enjoined the FDA from taking any final agency action, that is granting any ANDAs at issue, from April 11, 2007 until April 13, 2007 at 5:00 p.m. to "enable the court to rule formally on the plaintiff's application for TRO."

Zydus strongly believes that the Court's decision in enjoining the FDA in favor of Mylan is completely erroneous. The grounds on which Mylan contends that there is a substantial likelihood of succeeding on the merits of its claims against FDA are without any scientific or legal merit. The FDA should move the Court to withdraw its present order and deny Mylan its request for a TRO to prohibit approval of any ANDAs during its own designed 180-day exclusivity period.

Zydus expressly disagrees with Mylan's interpretation of the 180-day exclusivity and pediatric exclusivity provisions of the Food, Drug and Cosmetics Act. Mylan's contention that it is entitled to a 180-day exclusivity, even though the underlying patent has expired is clearly erroneous, and clearly flies against congressional intent. A major part of the congressional interest when enacting the Hatch Waxman Act was to speed up the introduction of low-cost generic drugs into the marketplace by creating incentive of a 180-day marketing exclusivity to the generics challenging patents through a paragraph IV certification, thereby facilitating faster entry before the expiry of patents on name brand product. In doing so, Congress did not intend to postpone generic entry beyond the life of the patent.

Such intention of the Congress is clearly manifested in 21 U.S.C. § 355(j)(5)(D)(i)(VI), which states that the 180-day exclusivity period is forfeited if all of the patents as to which the ANDA applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

Zydus firmly believes that Mylan's interest in extending the 180-day exclusivity beyond the date of expiry of the patents is clearly in conflict with Congressional intent. Zydus respectfully submits that by promoting such interest, the Court has acted erroneously.

Zydus believes that the 180-day exclusivity awarded to Mylan is forfeited by the provisions of the Medicare Amendment Act, 2003 codified at 21 U.S.C. § 355. Zydus submits that extending 180-day exclusivity beyond the expiry date of the patent is a clear violation of 21 U.S.C. § 355(j)(5)(D)(i)(VI).

C. Environmental impact

The action requested by this petition qualifies for a categorical exclusion under 21 C.F.R. § 25.31(a). Therefore, we submit, an environmental assessment is not required.

D. Economic impact

Pursuant to 21 C.F.R. § 10.30(b), information in the economic impact of this action requested by this petition will be submitted if requested by the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted



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