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Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20855

EMERGENCY PETITION FOR STAY OF ACTION

On behalf of Cobalt Laboratories Inc. and Cobalt Pharmaceuticals Inc. ("Cobalt"), the undersigned respectfully submit this petition requesting that the Agency stay approval of any and all subsequent abbreviated new drug applications ("ANDAs") for Acarbose Tablets 25 mg, 50 mg, and 100 mg until after the natural expiration of Cobalt's 180-day exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv), in order to prevent substantial and irreparable harm to Cobalt. *See* 21 C.F.R. § 10.35; 21 U.S.C. § 355. The basis for this petition is set forth below, and in Cobalt's comment, dated October 17, 2007, submitted to the Office of Generic Drugs ("OGD") under reference number OGD #07-1254, which comment is incorporated by reference herein.[1]

As required by 21 C.F.R. § 10.20, we include an original and 4 copies of this emergency petition for stay of agency action.

A. Decision Involved And Action Required.

This petition pertains to all subsequent ANDAs for acarbose tablets in any strength, all of which are subject to Cobalt's 180-day exclusivity. FDA must delay approval of all subsequent acarbose ANDAs until the natural expiration of Cobalt's 180-day exclusivity, which remains intact and has not been triggered or otherwise forfeited. Such relief is necessary

[1] Cobalt previously and properly submitted this Emergency Petition for Stay of Action as part of its comment, dated October 17, 2007, submitted to OGD under reference number OGD #07-1254. At the express request of OGD, Cobalt is hereby re-submitting its petition to Dockets Management.

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to prevent substantial and irreparable harm to Cobalt. *See* 21 C.F.R. § 10.35. Cobalt satisfies the requirements for such a stay.

B. Statement Of Grounds.

1. Cobalt Will Suffer Irreparable Injury.

Cobalt faces imminent substantial and irreparable injury in the absence of a stay. Cobalt indisputably submitted the first ANDA for acarbose tablets in all strengths with a so-called "paragraph IV certification" to the only Orange Book-listed patent for the brand product, Precose® Tablets: U.S. Patent No. 4,904,769 ("the '769 patent")—for which information remains listed in the Orange Book, as it lawfully must. As such, Cobalt is the "first applicant" entitled by statute to the critical 180-day generic marketing exclusivity that Congress created as a reward and incentive for undertaking the risk and expense of launching the first challenge to a listed patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Cobalt's exclusivity begins to run upon commercial marketing of its ANDA product. Because Cobalt has not yet commercially marketed its product, Cobalt's exclusivity remains intact and has not been triggered. Nor, for the reasons stated in Cobalt's comment submitted to OGD under reference number OGD #07-1254, has Cobalt otherwise forfeited its exclusivity. Accordingly, all subsequent paragraph IV acarbose ANDAs remain subject to, and cannot be approved prior to the expiration of, Cobalt's exclusivity. Any attempt by FDA to approve a subsequent ANDA in the face of Cobalt's exclusivity would be arbitrary, capricious, an abuse of discretion and contrary to law, in violation of both the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act.

Unless a stay is granted, subsequent applicants may attempt to circumvent Cobalt's exclusivity rights and seek immediate approval based on an unlawful interpretation and application of one or more of the forfeiture provisions added to Hatch-Waxman by the 2003 Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003). Thus, Cobalt could lose its exclusivity rights, and with those rights, the reward that Congress intended for challenging the '769 patent. In fact, it is Cobalt's understanding that a subsequent applicant may be seeking approval imminently, despite Cobalt's exclusivity. The only way to prevent this irreparable harm is through a stay.

2. Cobalt's Case Is Not Frivolous And Is Being Pursued In Good Faith.

Cobalt's case is not frivolous, and it is being pursued in good faith. Under the controlling statute, FDA must enforce Cobalt's exclusivity rights, which have not been triggered or forfeited.

3. Cobalt Has Demonstrated Sound Public Policy Grounds Supporting The Stay.

Congress designed Hatch-Waxman "to get generic drugs into the hands of patients at reasonable prices--fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Congress created the ANDA approval procedure. *See* 21 U.S.C. § 355(j)(2)(A). Congress also recognized that the only way for a generic company to market before patent expiration is to challenge the validity or scope of that patent in court. Such challenges are both risky and expensive. Congress, therefore, created the 180-day generic exclusivity period to "encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents . . . ." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000); *see also Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005) (stating that 21 U.S.C. § 355(j)(5)(B)(iv) "provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to 'design around' patents to find alternative, non-infringing forms of patented drugs"), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007); *Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 461 (D.D.C. 1999) (noting that the "purpose of the exclusivity incentive and the entire ANDA regime is to make available more low cost generic drugs"); 64 Fed. Reg. 42873, 42877 (Aug. 6, 1999) (acknowledging that the 180-day period is "the incentive created by Congress for ANDA applicants to challenge patents").

Here, Cobalt accepted the *quid pro quo* that Congress created with the exclusivity incentive and filed the first ANDA with a paragraph IV certification challenging the '769 patent. As a reward, Congress intended that Cobalt reap the benefits of 180-day generic market exclusivity. Sound public policy requires FDA to safeguard that exclusivity and to preclude others from circumventing it based on unlawful interpretations of the forfeiture provisions.

4. The Delay Resulting From The Stay Is Not Outweighed By Public Health Or Other Public Interests.

"[T]he public's interest in the 'faithful application of the laws' outweigh[s] its interest in immediate access to [a competing] generic product." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998). This is particularly true where, as here, the statutory scheme provides for a delay in approval of other ANDAs as an incentive to encourage the patent challenges necessary to bring lower-priced generic drugs to market quickly. The public interest therefore strongly supports a stay. Moreover, a temporary stay will not harm others or the public. There are no currently approved acarbose ANDAs. Subsequent applicants cannot claim harm from staying an approval to which they were never statutorily entitled in the first place.

C. Conclusion.

Cobalt is statutorily entitled to the 180-day exclusivity for all strengths of acarbose tablets. No triggering or forfeiture event has occurred with respect to that exclusivity.

FDA therefore must delay approval of all subsequent acarbose ANDAs until the expiration of Cobalt's exclusivity.[2]

Respectfully submitted,

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Bob West, *OGD*
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[2] Because this petition "relates solely to the timing of the approval of an application pursuant to [21 U.S.C. § 355](j)(5)(B)(iv)," this petition for emergency stay is exempt from the requirements found in 21 U.S.C. § 355(q). 21 U.S.C. § 355(q)(4)(A).