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VIA HAND DELIVERY & E-MAIL

Mr. Gary Buehler
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room – MPN II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Dockets Management Branch
Food and Drug Administration
Room 1061, Mail Stop HFA-305
5630 Fishers Lane
Rockville, MD 20852.

Re: FDA Docket # 2007N-0382
Ramipril Capsules and 180-Day Generic Drug Exclusivity

Dear Mr. Buehler:

On behalf of Cobalt Pharmaceuticals, Inc. ("Cobalt") we hereby submit a response to the combined Comment and Petition For Stay Of Action recently filed in Docket # 2007N-0382 by Apotex, Inc. ("Apotex") (the "PSA"). The PSA requests FDA to "stay [its] approval of any ANDA related to any generic [R]amipril until a decision is made by the FDA and/or a court of law from which no final appeal may be taken" as to Cobalt's entitlement to 180-day exclusivity under its approved ANDA for Ramipril Capsules (ANDA # 76-549). Apotex PSA at 1.

While the alleged statement of grounds is both confusing and wrong as to the relevant facts and law, Apotex appears to be contending that FDA can and should prevent Cobalt from launching its Ramipril Capsules unless and until the Agency makes some unspecified "decision" about Cobalt's continued right to 180-day exclusivity when and if it launches its Ramipril

2007N-0382 C8

Capsules product. Put more plainly, Apotex wants FDA "to deny Cobalt any approvals [sic] to launch any generic [ramipril] product until the FDA makes an informed and timely decision on whether Cobalt forfeited or relinquished any 180-day exclusivity it may have had." Apotex PSA at 3.

The PSA offers no substantive or procedural basis for FDA to take any action in connection with the timing of commercialization under Cobalt's approved ANDA, nor does it add anything to the public record to assist FDA's ongoing consideration of related exclusivity issues. While the PSA is without merit, several key points are noted below.

Discussion

I. There Is No Pending Action For FDA To Stay In Connection With Cobalt's ANDA

In asking FDA to "stay the approval of any [Ramipril] ANDA" pending a "decision" on Cobalt's right to 180-day exclusivity, the PSA ignores the fact that Cobalt's ANDA for Ramipril Capsules has already been approved and thus would not be affected by the requested action. At the time the ANDA was approved, Cobalt also was entitled to 180 days of marketing exclusivity, to be triggered either by the launch of Cobalt's product or a final decision of a court holding the relevant patent not infringed, unenforceable, or invalid. Although, the statutory mechanism for effecting exclusivity prohibits FDA from approving any other ANDAs during that period, there is no pending Cobalt ANDA for FDA to stay or deny.

There also is no basis for FDA to "deny Cobalt any approvals [sic] to launch" its generic Ramipril Capsules as Apotex requests. Apotex does not — and could not — cite any authority for FDA to approve, much less deny, the actual launch of an approved generic drug, nor has FDA ever asserted any such power of pre-launch review. To the contrary, once FDA has approved an ANDA, commercial decisions as to whether and when to launch a given product are and should remain solely within the ANDA holder's business judgment.

Moreover, the fact that Cobalt's ANDA is currently listed in the "discontinued products" section of the Orange Book provides no basis for FDA to issue a stay in response to Apotex's PSA. To the contrary, listing a product in the Orange Book as "discontinued" does not alter the status of the underlying ANDA in any way. Again, when a product has been listed as discontinued for other than safety or efficacy reasons, the ANDA holder remains free to begin or resume marketing the product at any time and for any reason without prior notice to FDA, much less prior approval.

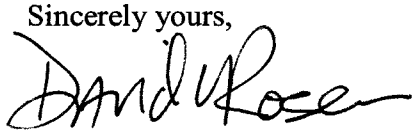
II. Apotex Offers No Persuasive Grounds For Forfeiture Of Cobalt's Marketing Exclusivity

Apart from Apotex's failure to identify any FDA action that could be stayed in the present circumstances, the PSA also fails to offer any new or persuasive information or arguments for stripping Cobalt of its statutory right to a 180-day exclusivity period for Ramipril Capsules. In essence, the PSA is no more than a colorful rehash of previous comments that Cobalt has already addressed and refuted, coupled with Apotex's speculation that Cobalt may have imminent plans to market Ramipril Capsules. Notwithstanding Apotex's characterization of any market launch as a "pre-emptive strike" planned in bad faith "to circumvent the FDA decision of Cobalt's death by launching something early," (Apotex PSA at 2), Cobalt has every right to launch a product under its approved ANDA at any time. The fact that Cobalt's right to exclusivity is contested by Apotex and other holders of subsequently-filed ANDAs is hardly surprising, and certainly does not — and should not — constrain Cobalt from legally marketing an approved product.

Conclusion

It remains Cobalt's position that FDA should take no action to grant final approval to any subsequent ANDA applicant for Ramipril Capsules until the expiration of Cobalt's 180-day exclusivity, to be triggered by the final decision of a court or Cobalt's commercial launch. Apotex's request for a stay of agency action fails to identify any pending action available to the FDA that could prevent or delay a planned commercial launch of Cobalt's approved Ramipril Capsules, nor does it present any legal or policy basis for FDA to do so at the behest of potential generic competitors. Accordingly, the PSA should be denied. Finally, Cobalt again respectfully submits that its plans for launch are confidential business information, but which Cobalt would be willing to discuss with FDA if requested.

Sincerely yours,



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cc: Elizabeth Dickinson, Esq.