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VIA MESSENGER

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: FDA Docket Number 2007N-0382
Comments regarding 180-day generic drug exclusivity for Ramipril Capsules

Dear Sir or Madam:

We are writing on behalf of CVS Caremark Corporation ("CVS Caremark") to request that the Food and Drug Administration ("FDA") take immediate action to ensure that generic versions of ramipril are approved and available to consumers.

CVS Caremark is the largest provider of prescriptions and related healthcare services in the nation. The Company fills or manages more than one billion prescriptions annually. It operates 6,200 CVS/pharmacy stores; a pharmacy benefit management, mail order and specialty pharmacy division, Caremark Pharmacy Services; its retail-based health clinic subsidiary, MinuteClinic; and its online pharmacy, CVS.com. Access to generic drugs is a critically important element of cost-effective pharmaceutical care. The availability of lower cost therapeutic alternatives is important for patients and payors alike as escalating costs continue to burden the healthcare system.

As you know, ramipril capsules are currently marketed by King Pharmaceuticals, Inc. ("King") under the brand name ALTACE®. In 2003, Cobalt Pharmaceuticals, Inc. ("Cobalt") was the first company to file an Abbreviated New Drug Application ("ANDA") referencing King's ALTACE® capsules that contained a Paragraph IV certification to a patent listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") claiming ALTACE®. It is our understanding that several other companies filed ANDAs for generic versions of ALTACE® after Cobalt filed its application. Because Cobalt was the first to file an ANDA containing a Paragraph IV certification, under Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"), Cobalt appeared to be entitled to a 180-day exclusivity period delaying the approval of the other ANDAs.

However, the subsequent settlement of the patent infringement litigation between King and Cobalt, followed by Cobalt's failure to market its generic product, raises serious questions about

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whether Cobalt remains entitled to such exclusivity, from both a legal and a public policy perspective.[1] CVS Caremark respectfully requests that FDA thoroughly and immediately review this matter, as every day of delay prevents consumers and payors from gaining access to lower cost therapeutically-equivalent alternatives to ALTACE®.

Congress enacted the Hatch-Waxman Amendments in order to expand access to lower cost therapeutic alternatives to brand-name drugs. As part of this effort to open the marketplace to generic competition, the 180-day exclusivity provisions were designed to reward generic companies that enter the market as the result of successfully challenging listed patents. However, to permit a company such as Cobalt to indefinitely "park" its exclusivity without actually marketing a product, and then, through its apparent agreement with King, to block other generics from coming to market, stands in direct contradiction to Congress' intent.

Indeed, as Congress has indicated repeatedly, through the passage of the Hatch-Waxman Amendments, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), and, most recently, the Food and Drug Administration Amendments of 2007, expanded access to generic drugs is of paramount importance to the public interest. Further, generic drug reform in recent years has attempted to address situations like this, where companies attempt to circumvent the original legislative intent of the Hatch-Waxman Amendments. With the passage of the MMA, Congress added forfeiture provisions to prevent the first applicant submitting an ANDA with a paragraph IV certification from indefinitely blocking others by "parking" its 180-day exclusivity. These provisions were added only after careful consideration of innovator patent rights, the rights of generic competitors, and the clinical and public policy benefits of access to generic drugs. However, since the Cobalt ANDA was filed prior to the passage of MMA, technically speaking, these new forfeiture provisions do not apply. Despite this issue of timing, CVS Caremark believes that it is imperative that FDA implement the Hatch-Waxman Amendments in such a way that the Congressional intent and the good public policy supported by the law be realized in the current situation. FDA has the authority to – and, indeed, from a public policy perspective should – take action to ensure that consumers have timely access to lower cost generic drugs.

In this case, significant questions remain regarding whether Cobalt remains eligible for 180 days of exclusivity for its generic product, as well as whether FDA should remove the applicable patent from the Orange Book and grant final approval to the tentatively approved ANDAs.

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[1] CVS Caremark does not contend that all settlements between a pioneer and generic company over the marketing of the generic product necessarily warrant the loss of 180-day exclusivity. However, we believe that the facts at hand certainly warrant, at the very least, FDA's careful consideration as to whether Cobalt is still entitled to such exclusivity.

We respectfully request that the Agency take action to resolve these issues in an expedited manner so as to provide consumers with timely access to generic ramipril products.

Very truly yours,

Wayne H. Matelski/jct

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Counsel to CVS Caremark Corporation