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Via Hand Delivery

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

Re: Docket No. 2003P-0121; Supplement to Biovail Citizen Petition

Through the undersigned counsel, Biovail Corporation wishes to reaffirm its interest in receiving a substantive response to its Citizen Petition 2003P-0121 (dated March 26, 2003). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) neither ameliorates the problem nor precludes all of the relief options sought in the petition (*e.g.*, allowing the patent court to extend or shorten the 30-month delay). Thus, the issues presented in the petition remain current and should be resolved.

The above-reference petition urges FDA to require submitters of Abbreviated New Drug Applications (ANDAs) that include certifications of patent non-infringement (Paragraph IV Certifications) to include in all ANDA amendments a certification that the applicant will provide to the NDA holder and patent owner: (1) a new notice of patent certification; or (2) if the amendment does not involve any changes to the chemistry, manufacturing, and controls (CMC) section of the ANDA, a notification to that effect. Requiring a new patent certification whenever the CMC portion of an ANDA is amended will allow the NDA holder and patent owner to ensure that the impact of the amendment on patent infringement issues is addressed promptly.

The need for this certification is clear:

Amendments to a pending ANDA can mean that the proposed drug product has changed in important respects from the product described in the original ANDA, and these changes may have significant patent infringement implications. Since such changes may affect the course of the patent infringement litigation, prompt disclosure is essential to resolving any question about the accuracy of the patent certification and the factual/legal justifications presented in the notice of certification. The fact that an original ANDA contained a Paragraph IV certification and, after amendment, the appropriate certification is still a Paragraph IV

certification is inadequate to conclude that the certification is still
“accurate.”

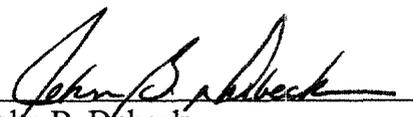
(Petition, at 5-6).

Biovail believes the abuses described in the petition (*i.e.*, an ANDA applicant modifying its application during the FDA review, including after receiving tentative approval) remains a legitimate concern. Such amendments raise serious questions about whether the product the generic applicant seeks to have approved is the same as the one described in the initial notice of patent certification. The relief sought in the petition would provide the NDA holder and patent owner the opportunity to consider whether and how the amendments to the ANDA affect patent infringement issues.

While the MMA substantially amended the ANDA regulatory scheme, it did not alter the provisions allowing the patent court to adjust the 30-month stay based on a party’s failure “to reasonably cooperate in expediting the [patent] action.” Thus, the primary basis for providing the relief sought in the petition is still available.¹

In Biovail’s view, the MMA did not resolve the policy concerns raised in the petition. Since the relevant statutory provisions have not changed, FDA is respectfully urged to respond to the petition on its merits.

Respectfully submitted,


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¹ Biovail acknowledges that the other option described in the petition (filing a new patent infringement suit to obtain a new automatic 30-month delay) may not be permitted in light of the MMA.