



28 January 2005

BY FEDERAL EXPRESS

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

Re: Docket No. 2004P-0324/CP1: THIRD AMENDMENT TO CITIZEN PETITION

Ladies/Gentlemen:

The undersigned Petitioner, Dey, L.P. ("Dey"), holder of New Drug Application ("NDA") 20-950 for the inhalation solution drug DuoNeb<sup>®</sup> (ipratropium bromide, albuterol sulfate) submits in quadruplicate this third amendment to its above-identified Citizen Petition, initially filed July 15, 2004, with amendments dated August 30, 2004 and December 3, 2004, pursuant to Section 505(j)(5) (B)(iii) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(B)(iii), as amended, and FDA regulations 21 C.F.R. §§ 314.107(b)(3), 10.20, 10.25 and 10.30.

Since the filing of the second amendment to the petition, Dey has learned that Ivax Laboratories, Inc. ("Ivax") has (i) filed comments opposing Dey's petition on the 30-month stay issue, and (ii) filed its own citizen petition (Docket No. 2004P-0520/CP1) concerning eligibility for 180-day exclusivity for generic versions of DuoNeb<sup>®</sup>.

Accordingly, having reviewed these submissions by Ivax, Dey files this third amendment in support of its instant petition as noted in the additional clarification below, and in reply to Ivax's comments. (Simultaneously with this third amendment, Dey is filing comments opposing Ivax's petition).

1. Additional Clarification by Dey

Upon further consideration, Dey seeks rulings from FDA that:

- (a) Ivax's ANDA 76-724 for ipratropium bromide and albuterol sulfate inhalation solution is subject to a 30-month stay of final approval, for the reasons set forth in this third amendment, or alternatively, for the reasons set forth in Dey's original citizen petition dated July 15, 2004

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AMD3 An Affiliate of EMD, Inc.

(for purposes of these alternative reasons, this is a revival of Dey's initial petition); and

- (b) Eon Labs' ANDA 76-867 for ipratropium bromide and albuterol sulfate inhalation solution is also subject to a single 30-month stay of final approval, for the reasons stated in the first and second amendments to Dey's petition dated August 30 and December 3, 2004 respectively.

2. **The MMA and FDA's Guidance Require a 30-Month Stay for Ivax**

A fresh analysis of 21 U.S.C. § 355(j)(5)(B)(iii), as amended by the Medicare Prescription Drug and Modernization Act of 2003 (MMA), supported by FDA's "Guidance for Industry-Listed Drugs, 30-Month Stays and Approval of ANDAs and 505(b)(2) NDAs under Hatch-Waxman" (October 2004), compels the conclusion that Ivax's ANDA must be stayed for 30 months.

- Amended Section 355(j)(5)(B)(iii) (see Dey's July 15, 2004 petition at 4; December 3, 2004 amendment at 2) begins with the words:

**"If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii)..."**

By virtue of this language, it is clear that amended Section 355(j)(5)(B)(iii) provides for a 30-month stay under the conditions described in the section **only for an ANDA containing a paragraph (IV) certification.**

- Here, Ivax's ANDA did not contain a paragraph IV certification until December 9, 2004 (see Dey's August 30, 2004 amendment at 2; Ivax's petition in Docket No. 2004P-0520 at 1-2). This was nearly two months after Dey's '842 patent was submitted to FDA for listing in the Orange Book on October 14, 2004.\* Thus, the pertinent condition of amended Section 355(j)(5)(B)(iii) is **satisfied** – the '842 patent was submitted for listing **before** Ivax's ANDA contained a paragraph IV certification.

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\* Under FDA practice, the '842 patent is deemed listed as of its October 14, 2004 submission date, even though the patent may not have appeared in the electronic Orange Book on FDA's website until November 6, 2003 (see Eon's comments on Ivax's petition, at 1).

- The parenthetical language in amended Section 355(j)(5)(B)(iii) (“excluding an amendment or supplement to the application”) is immaterial. Ivax’s ANDA when filed in April 2003 did not contain a paragraph IV certification. Under the above bolded statutory language, only an ANDA with a paragraph IV certification is subject to the provisions of amended Section 355(j)(5)(B)(iii), including a 30-month stay.
- The above interpretation is buttressed by FDA’s October 2004 Guidance for Industry, under which a 30-month stay of approval will apply if the patent was submitted to FDA on or after the date the ANDA or 505(b)(2) application **with a paragraph IV certification to the patent** was submitted (see Guidance at 9; Dey’s December 3, 2004 amendment at 3).

**Conclusion**

- ◆ Ivax’s ANDA is subject to a 30-month stay for the reasons stated herein or, alternatively, for the reasons stated in Dey’s original July 15, 2004 citizen petition;
- ◆ Eon’s ANDA is also subject to a 30-month stay for the reasons stated in Dey’s August 30 and December 4, 2004 amendments to Dey’s citizen petition.

Sincerely yours,

DEY, L.P.



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