



03 December, 2004

BY FEDERAL EXPRESS

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

Re: Docket No. 2004-0324/CP1: SECOND 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 Second Amendment to its above-identified Citizen Petition, filed July 15, 2004 and initially amended August 30, 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. §§ 314.95(a)(3), 10.20, 10.25 and 10.30.

1. Clarification

In its First Amendment to this Citizen Petition filed August 30, 2004, Dey requested written confirmation from the Food and Drug Administration ("FDA") that ANDA 76-867 submitted by Eon Labs, Inc. ("Eon") for a generic formulation of Dey's drug product DuoNeb<sup>®</sup> is subject to a 30-month stay of approval.

Since the filing of the First Amendment, Dey has been requested by FDA to clarify whether we are requesting a response to the issue raised by the initial Citizen Petition involving Ivax Laboratories' ANDA for a generic version of DuoNeb<sup>®</sup>, and/or the issue raised by the First Amendment to the Petition involving Eon's ANDA.

This is to clarify that Dey at this time seeks only a written response to the issue raised in the First Amendment to the Petition, namely, *whether Eon's ANDA is subject to a 30-month stay of final approval.*

2. Additional Analysis

In the first amendment to the petition filed August 30, 2004, Dey maintains that a

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An Affiliate of EMD, Inc.

30-month stay of final approval of Eon's ANDA is required under 21 U.S.C. § 355(j) (5)(B)(iii), as amended by the Medicare Modernization Act on December 8, 2003, because Dey's '842 patent was listed in the Orange Book on 14 October, 2003, a date approximately six weeks before Eon's ANDA containing a paragraph IV certification was received for filing on 29 November, 2003. [First Amendment to Citizen Petition, pp. 2-3]. As noted in the First Amendment, Dey believes that the proper interpretation of Eon's ANDA being "submitted," in the context of amended Section 355(j)(5)(B)(iii), is the date when this ANDA was "received for substantive review." *Id*; see 21 C.F.R. § 314.101(b).

However, even assuming the term "submitted" in amended Section 355(j)(5)(B)(iii) could be read to mean the date Eon initially forwarded its ANDA to FDA (3 October, 2003), because of some perceived ambiguity in the term "submitted" or the statutory language "which the Secretary later determines to be substantially complete," the result would not change.

Eon's original ANDA when submitted on 3 October, 2003 did not and could not contain a paragraph IV certification, because the '842 patent was not issued or submitted for Orange Book listing until 14 October, 2003. Eon's ANDA did not contain a paragraph IV certification until it was received for substantive review by FDA on 29 November, 2003, well after the '842 patent was listed. Applying amended Section 355(j)(5)(B)(iii) to these facts demonstrates that a 30-month stay is still warranted. As the statute provides in pertinent part:

"If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately, unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted, the approval shall be made effective on the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) ..." (emphasis supplied).

Under this language, if a patent is submitted to FDA for listing in the Orange Book prior to the date an ANDA containing a paragraph IV certification is submitted, the 30-month stay applies. Since Eon's ANDA did not include a

paragraph IV certification until after the '842 patent was listed, a 30-month stay went into effect.

This result is also buttressed by FDA's recently-issued "Guidance for Industry-Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (October 2004). This Guidance states: "[n]o 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" (Guidance, p. 9). It follows that where, as here, the '842 patent was submitted to FDA for Orange Book listing **before** the date when **Eon submitted an ANDA containing a paragraph IV certification against the '842 patent**, the 30-month stay of approval **does apply**.

3. Conclusion

For the foregoing reasons and those set forth in the first amendment to the instant Citizen Petition, Dey requests a written ruling from FDA confirming that a 30-month stay of final approval applies to Eon's ANDA 76-867 for a generic version of DuoNeb<sup>®</sup>, *i.e.*, this ANDA cannot be granted final approval, assuming all ANDA requirements are met, until 20 June, 2006, the date that is 30 months from the date when Dey received notice of Eon's paragraph IV certification against the '842 patent (20 January, 2004).

Sincerely,

DEY, L.P.

By *Michelle A. Carpenter*  
Michelle A. Carpenter, J.D.  
Vice President, Regulatory and Clinical Affairs

cc: Gary J. Buehler  
Elizabeth H. Dickinson, Esq.  
Frederick S. Ansell, Esq.