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**Shashank Upadhye, Esq.**  
Vice President  
Head of Intellectual Property and  
Regulatory

Tel + 1 609 627 8511  
Fax + 1 609 627 8684  
e-mail:  
shashank.upadhye@sandoz.com

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

Re: Docket No. 2004P-0520 (180-Day Exclusivity for Ipratropium Bromide  
and Albuterol Sulfate Inhalation Solution)

Dear Food and Drug Administration:

Sandoz, Inc. (Sandoz) (formerly Eon Labs, Inc. (Eon)) submits this additional comment in opposition to the citizen petition filed by IVAX Pharmaceuticals, Inc. (IVAX), dated 19 Nov. 2004. Specifically, this comment responds to the arguments raised in IVAX's 11 Aug. 2005 comment (IVAX comment). For the reasons discussed below, and in Eon's earlier (17 Dec. 2004, 02 Apr. 2005, and 11 Jul. 2005) comments, incorporated by reference herein, IVAX's petition should be denied.

Sandoz

506 Carnegie Center,  
Suite 400  
Princeton, NJ 08540

www.us.sandoz.com

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a Novartis company

IVAX starts by positing that this matter involves a “limited and unique set of circumstances” (IVAX comment at 1). The purported “uniqueness” apparently arises from the fact that Sandoz, but not IVAX, is subject to a 30-month delay of ANDA final approval, which situation (it is said) the agency must address through “interpretation.” We disagree. The effective dates of the different MMA provisions are clear and explicit. Under the plain terms of the MMA: (1) Sandoz, but not IVAX, is subject to a 30-month delay of ANDA final approval; (2) the MMA’s “new” notice of Paragraph IV certification provisions apply to both Sandoz and IVAX; and (3) the MMA’s “new” 180-day exclusivity eligibility provisions do not apply. Congress has spoken, and spoken clearly. There is neither room -- nor need -- for the type of “interpretation” that IVAX seeks.

Next, IVAX argues:

Had the MMA exclusivity provisions been applicable to IVAX’s ANDA, the wording of the statute would have dictated this result [that IVAX is eligible for 180-day exclusivity] because Congress provided an express enforcement provision for the MMA notice requirements in the definition of “first applicant,” which directs that exclusivity be determined based not on the date of physical submission of the paragraph IV certification but rather on the date that FDA determines that the certification was both submitted and “lawfully maintain[ed].” Here, however, the MMA exclusivity provisions are inapplicable and the MMA notice provisions must be enforced under the pre-MMA exclusivity provisions. The outcome, nevertheless, is the same.

IVAX comment at 2 (footnote omitted).

IVAX is correct on one -- and only one -- point: that the MMA’s 180-day exclusivity provisions do not apply to the current situation. But if they did, it is plain that Sandoz, not IVAX, would be entitled to 180-day exclusivity. Under the MMA’s “new” 180-day exclusivity

provision, only a “first applicant” is eligible for 180-day exclusivity. “First applicant” is defined as follows:

As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV certification] for the drug.

21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). Here, Sandoz submitted the first substantially complete Paragraph IV application. Sandoz also “lawfully maintain[ed]” its Paragraph IV ANDA by providing notice of its Paragraph IV certification in accordance with the MMA’s notice provisions (by providing notice not later than 20 days after the date of the postmark on the notice with which FDA informed Sandoz that its ANDA has been filed, 21 U.S.C. § 355(j)(2)(B)(ii)(I)). Thus, IVAX’s argument fails and does not support the result it seeks.

IVAX continues to make its “date certain” argument in a futile effort to support its position. As stated in our prior comments, that argument has no merit. The only reasonable interpretation of the MMA’s notice of Paragraph IV certification requirements is that the 180-day exclusivity “priority date” for a Paragraph IV certification contained in an original ANDA that is subsequently found to be acceptable for substantive review (like Sandoz’s) is the date on which the ANDA was initially received by FDA. Likewise, the only reasonable interpretation is that the 180-day exclusivity “priority date” for a Paragraph IV certification contained in an amendment to a pending ANDA where the sponsor provides timely notice (like IVAX’s) is the date of submission and notice. While the MMA provided additional specificity regarding the timing of notice of a Paragraph IV certification for both original and amended ANDAs, it did not change the underlying nature of the pre-MMA notice requirements. Thus, in no way did the MMA “remove[] the distinction” or “eliminate[]

the distinction” between original ANDAs and ANDA amendments (IVAX comment at 3, note 8, and 4).

Moreover, contrary to IVAX’s assertions, Sandoz is not advocating a “proposed change in the agency’s interpretation” (IVAX comment at 3), because there is no need for such a change. FDA’s longstanding interpretation compels the conclusion that Sandoz, not IVAX, is entitled to 180-day exclusivity.<sup>1</sup>

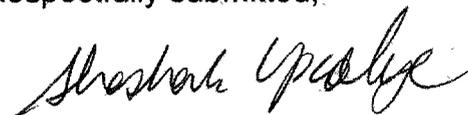
Finally, IVAX would have the agency believe that there would be some fundamental unfairness if it does not receive 180-day exclusivity simply because it was the first to file an ANDA for a generic version of DuoNeb. In a word, nonsense. The undisputed purpose of the 180-day exclusivity provisions of the FDC Act is to reward the first ANDA sponsor that helps open the door for generic competition by challenging an Orange Book patent on the innovator product by means of a Paragraph IV certification, not to reward the first sponsor to file an ANDA of any type. Here, Sandoz was the first to challenge Dey’s ‘842 patent after that patent was listed in the Orange Book. IVAX did not do so until about ten days later. Thus, Sandoz, not IVAX, “deserves” the 180-day exclusivity “reward” by virtue of its diligence in being the first to challenge Dey’s patent. In fact, to use IVAX’s colloquialism (IVAX comment at 4), IVAX is the “Johnny-come-lately” patent challenger that is seeking to “derail” the legitimately earned exclusivity of Sandoz, the first Paragraph IV filer. Thus, even when viewed from 10,000 feet and without paying attention to the legal and regulatory intricacies involved, IVAX does not have any legitimate complaints.

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<sup>1</sup> As noted in Eon’s 17 Dec. 2004 comment at 3-4, IVAX should be estopped from disputing FDA’s longstanding interpretation, which it strenuously supported in litigation.

For these reasons and those previously stated by Sandoz, IVAX's petition must be denied. We appreciate this opportunity to comment and look forward to FDA's decision finally denying IVAX's petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shashank Upadhye". The signature is written in a cursive style with a large, sweeping initial 'S'.

Shashank Upadhye, Esq.