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11 July 2005

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

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

Dear Food and Drug Administration:

Eon Labs, Inc. (Eon) submits this additional comment in opposition to the Citizen Petition submitted by IVAX Pharmaceuticals, Inc. (IVAX), dated 19 Nov. 2004. Specifically, this comment responds to the arguments raised in IVAX's 24 May 2005 submission. For the reasons discussed below, and in Eon's 17 Dec. 2004 and 02 Apr. 2005 comments, IVAX's petition should be summarily denied.

IVAX continues to argue about its concept of a "statutory 'date certain'" (IVAX comment at 1), while utterly failing to provide any citations of support and despite Eon's invitations to do so. For the reasons set forth in our 02 Apr. 2005 comment, the MMA did not establish a "date certain" as that term ordinarily would be understood with respect to Eon's Paragraph IV ANDA.

More importantly, even if we accept IVAX's "date certain" views for purposes of discussion, those views do not support the ultimate position that IVAX advances. "Date certain" or not, IVAX overlooks the fundamental distinction in the MMA between original ANDAs containing Paragraph IV certifications (like Eon's) and amendments to pending ANDAs to include a new Paragraph IV certification (like IVAX's). Contrary to IVAX's unsupported assertion, in no way has "Congress eliminated the distinction between original ANDAs and ANDA amendments" (IVAX's 25 Feb. 2005 comment at 2). IVAX provides no support for this bald

statement. Under the MMA, the sponsor of an original ANDA with a Paragraph IV certification cannot give notice to the patentee and NDA sponsor until it has been notified by FDA that the ANDA has been determined to be substantially complete and acceptable for substantive review; the ANDA sponsor then has a 20-day window for providing notice in a timely fashion. In comparison, when the sponsor of a pending (already accepted for substantive review) ANDA amends to include a new Paragraph IV certification, it is required to provide notice “at the time” that it amends its ANDA. This is plain.

As discussed in our earlier comments, the only reasonable interpretation of these provisions is that the applicable “priority date” for 180-day exclusivity purposes for the sponsor of an original ANDA with a Paragraph IV certification is the date on which the ANDA was initially received by FDA, subject to the condition that the sponsor provide timely notice in the statutory 20-day window. IVAX has not countered these arguments at all despite Eon’s invitations to do so.

In our 02 Apr. 2005 comment at 3, we posed a hypothetical that establishes the folly of IVAX’s position. We described how IVAX’s interpretation would result in surplus language in the MMA’s new definition of “first applicant.” Rather than address our example head on, IVAX attempts to shift gears to discuss drug-by-drug versus patent-by-patent exclusivity. We agree with IVAX that the language in question in the new definition of “first applicant” (“on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted for approval of a drug”) “is the linchpin of the drug-by-drug (as opposed to patent-by-patent) approach to exclusivity taken by Congress in the MMA” (IVAX comment at 2, footnote omitted). In fact, IVAX’s “linchpin” observation further supports Eon’s position. The example set forth in our 02 Apr. 2005 comment demonstrated that IVAX’s contorted interpretation can only work if the quoted language is ignored and treated as surplusage. Not only would that interpretation violate the recognized principle of statutory interpretation that surplus language is not favored (see discussion in our 02 Apr. 2005 comment at 4), but it would also gut the “linchpin” of the MMA’s drug-by-drug approach to exclusivity. Simply stated, IVAX has no good answer for the hypothetical in our 02 Apr. 2005 comment and how that hypothetical, under IVAX’s interpretation, results in surplus language. All that IVAX can do is to attempt to divert the agency’s attention through “smoke and mirrors.”

Finally, as the heading for Section III of this letter, IVAX states: “IVAX Agrees that FDA Should follow the Approach that It Takes under the Pre-MMA Provisions.” IVAX comment at 2. FDA’s pre-MMA approach, for an original ANDA containing a Paragraph IV certification, is that a sponsor’s priority date for 180-day exclusivity purposes is the date on which the ANDA was first received by FDA, assuming it was subsequently determined to be substantially complete and acceptable for review.

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

Respectfully submitted,

A handwritten signature in black ink, reading "Shashank Upadhye". The signature is written in a cursive style and is positioned to the left of a vertical line.

Shashank Upadhye, Esq.  
Vice President and Counsel

By: electronic submission and mail