

May 24, 2005

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

Re: Docket Number 2005P-0520 (Citizen Petition) – Second Submission of  
Comments by IVAX Pharmaceuticals

Dear Sir or Madam:

These comments are submitted on behalf of IVAX Pharmaceuticals, Inc., (IVAX) in response to a supplemental submission of comments by Eon Labs<sup>1</sup> (Eon Supp. Comments) regarding the Citizen Petition filed by IVAX on November 19, 2005.<sup>2</sup> IVAX's petition requests confirmation that IVAX is entitled to 180-day exclusivity with regard to ANDA No. 76-724 if IVAX was the first applicant to submit a paragraph IV certification and satisfy the statutory notice requirement for that certification.

Eon contends in its most recent comments that IVAX's petition should be denied because (1) there is no "date certain" for providing notice because the date is dependent on getting a letter from FDA, (2) IVAX's theory would render "surplusage" the MMA requirement that "first applicant" status be determined based on the date of submission of the first paragraph IV certification, and (3) FDA should follow the same approach that the agency takes regarding pre-MMA amendments. Eon is wrong on the first two points and right on the third.

**1. There Was a Statutory "Date Certain."**

Eon contends that there was no "date certain" for its notice requirement because (1) the date is dependent on the date that FDA acknowledges receipt for filing of an ANDA and (2) Eon did not know when it submitted its ANDA when that date would be. Eon Supp. Comments at 2.

Eon's misconstrues the concept of a "date certain." Although the notice date could not be determined at the time of submission of Eon's ANDA, it was a date certain under the statute because the date could be determined by operation of the statute. The statutory certainty of the date is not contingent on whether Eon was certain of the date when it filed its ANDA. The significance of a date certain is that it ultimately permits a clear and objective determination of the date at which notice must be provided to satisfy the terms of the statute.

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<sup>1</sup> These comments were apparently submitted via email on April 1, 2005. Eon's first submission of comments was dated December 17, 2004. Docket No. 2005P-0520: C1 (Dec. 17, 2004).

<sup>2</sup> Docket No. 2005P-0520: P1 (Nov. 19, 2004).

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## 2. The MMA Language Is Not “Surplusage.”

Eon contends that IVAX’s theory would render “surplusage” the MMA requirement that “first applicant” status be determined based on the submission of an ANDA “on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted.” Eon Supp. Comments at 3 (quoting new section 505(j)(5)(B)(iv)(ii)(bb)).

A reading of the MMA without this language demonstrates why it is not “surplusage” under IVAX’s interpretation. Without this language, the MMA provision would read:

As used in this subsection, the term “first applicant” means an applicant that [deleted language] submits a substantially complete application that contains and lawfully maintains a [paragraph IV certification] for the drug.

As is evident from this modification, the phrase that is deleted is necessary to convey the concept that the applicant must satisfy the “substantially complete” ANDA requirement *on the first day that any applicant satisfies that requirement for the same drug*. This qualification is hardly surplusage under IVAX’s proposed interpretation; it is the linchpin of the drug-by-drug (as opposed to patent-by-patent) approach to exclusivity taken by Congress in the MMA.<sup>3</sup>

## 3. IVAX Agrees that FDA Should follow the Approach that It Takes under the Pre-MMA Provisions.

Eon oddly argues that “it seems logical to assume (and for Congress to have assumed) that FDA would . . . adopt the same approach that it did for pre-MMA ANDA amendments to include a paragraph certification to a newly listed patent.” Eon Supp. Comments at 5 (emphasis in original).

Eon is, of course, correct. FDA’s pre-MMA approach was to determine the date of submission of the substantially complete ANDA *amendment* based on the date that the notice requirement was satisfied. That same approach should be taken under the MMA provisions, which require satisfaction of the notice requirement within 20 days of FDA’s notice that the original application has been filed.

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<sup>3</sup> To the extent that Eon focuses on the requirement that first applicant status be determined on the date on which the substantially complete ANDA is “submitted,” that same wording is used in the pre-MMA statute, where it has been interpreted by FDA to refer to the date on which the notice requirement is satisfied. See pre-MMA section 505(j)(5)(B)(iv) (delaying approval of an ANDA containing a paragraph IV certification “for a drug for which a *application has been submitted* under this subsection continuing such a certification”) (emphasis added). The substantially complete ANDA containing a paragraph IV certification is not deemed “submitted” until the notice requirement is satisfied.

Eon attempts to reinvent FDA's pre-MMA interpretation by suggesting that when, under the pre-MMA provisions, an applicant fails to provide notice simultaneously with the amendment of its ANDA, the applicant "loses" 180-day exclusivity and is penalized by being given a delayed priority date for determining exclusivity. Of course, FDA does not take the position that exclusivity is initially "lost" and then regained by being first to provide notice. The agency simply determines whether there is a substantially complete ANDA based on the date that the notice requirement is met. This is precisely what IVAX proposes should be the case for original ANDAs under the MMA notice provisions.

Eon also argues that, under IVAX's proposed interpretation of the statute, the requirement that notice be provided within 20 days would serve no useful purpose because "the 180-day exclusivity priority date would be the date the notice was sent,<sup>4</sup> without regard for whether [the applicant] complied with the statutory 20-day period." Eon Supp. Comments at 5. Of course, the requirement that notice be provided within 20 days applies not only to first filers, but also to the vast majority of ANDA applicants submitting paragraph IV certifications who are not first filers. *Everyone* is required to give notice within 20 days. Requiring that the exclusivity qualifying date be based on satisfaction of the notice requirement ensures that notice will be provided by first filers in as timely a manner as possible. This is precisely the reasoning behind FDA's interpretation of the pre-MMA notice provisions for ANDA amendments. In fact, Eon could make the same argument against FDA's pre-MMA policy (that the policy awards exclusivity regardless whether the applicant satisfies the statutory requirement that notice be provided on the date that the amendment is submitted, and thus renders that requirement irrelevant).

Respectfully submitted,



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<sup>4</sup> Under FDA's pre-MMA policy and under IVAX's proposal, notice is determined on the date that notice is *received* rather than the date on which notice is sent.

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**VIA FEDERAL EXPRESS**

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Comments by IVAX Pharmaceuticals

Dear Sir or Madam:

Please accept the attached comments (in four copies) submitted on behalf of  
IVAX Pharmaceuticals, Inc., pursuant to 21 C.F.R. § 10.35.

Sincerely,



David G. Adams