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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. submits this comment in opposition to Ivax's Citizen Petition dated 19 Nov. 2004; specifically, this comment responds to the arguments raised in IVAX's 25 Feb. 2005 submission. For the reasons discussed below and in Eon's 17 Dec. 2004 comment (incorporated by reference herein), IVAX's petition should be denied.

IVAX's principal point is that "where the statutory notice requirement is expressed as a command that notice be provided by a date certain, the applicant is deemed to have submitted a substantially complete application only when the notice requirement is satisfied." IVAX letter at 1-2 (footnote omitted). That

argument is based on the incorrect assumption that, for Paragraph IV certifications in original ANDAs (like Eon's), the MMA created a "date certain" for sending notice. That is simply not so. When Eon submitted its Paragraph IV ANDA in late November 2003 (under pre-MMA law), Eon had no idea of any "date certain" by which it would have to give notice. Nothing changed when the MMA became law on 8 Dec. 2003, as Eon still had no idea of the "date certain" by which it would have to give notice. Until Eon received FDA's letter stating that Eon's ANDA had been accepted for review in January 2004, Eon did not know that "date certain." Thus, the MMA did not establish a "date certain" as that term would ordinarily be understood.

In section 2 of its letter, IVAX states:

The MMA provisions on 180-day exclusivity are relevant only insofar as they reflect Congress' view at the time of the passage of the MMA that first applicant status should be determined based on the date of actual notice rather than on the date of submission of the ANDA.

IVAX letter at 3 (footnote omitted). Even if the MMA's 180-day provision and the new definition of "first applicant" were somehow applicable (which they are not as a matter of law), IVAX got it wrong.

It is useful to start with the MMA's statutory language. Section 505(j)(5)(B)(iv)(I) of the FDC Act [21 U.S.C. §355(j)(5)(B)(iv)(I)], as amended by the MMA, provides, in essence, that a "first applicant" is entitled to 180-day exclusivity:

Subject to subparagraph (D), if the application contains a [Paragraph IV certification] and is for a drug for which a first applicant has submitted an

application containing such certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

In new Section 505(j)(5)(B)(iv)(II)(bb), the term “first applicant” is defined:

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.

(Emphasis added.)

The folly of IVAX’s argument is easily illustrated by applying that language to the following hypothetical, which we will assume is governed by the MMA. Sponsor “A’s” original ANDA with a Paragraph IV certification to the ‘123 patent is received at FDA on Day 1; this is the first Paragraph IV certification to the ‘123 patent to be received by FDA. Sponsor “B’s” original ANDA with a Paragraph IV certification to the same patent is received by FDA on Day 2. On Day 50, FDA determines both ANDAs are substantially complete and acceptable for substantive review as of the dates of original receipt, and so notifies “A” and “B.” So “B” mails its notice of its Paragraph IV certification on Day 59, while “A” mails its notice on Day 60. Under IVAX’s interpretation, perversely “B” would have priority over “A” for 180-day exclusivity purposes because “B” sent notice before “A” sent notice. But this would render as surplusage language in the MMA’s definition of “first applicant” regarding “on the *first day* on which a substantially complete application containing a [Paragraph IV certification] is submitted.”

Under standard principles of statutory interpretation, an interpretation that results in surplus language is not favored. See, e.g., Babbitt v. Sweet Home Chapter of Communities for a Great Oregon, 515 U.S. 687, 698 (1995) (noting “a reluctance to treat statutory terms as surplusage”). If Congress had intended the result that IVAX advances, “first applicant” would have been defined quite differently, so that a “first applicant” is defined as the sponsor that is the first to complete both of the following two actions: (1) submit a substantially complete Paragraph IV ANDA to FDA, and (2) provide notice in accordance with the MMA’s notice requirements. The definition of “first applicant” would not have referenced the “first day” on which a substantially complete Paragraph IV ANDA is submitted to FDA.

Next, IVAX contends that, under Eon’s view, “the applicant submitting the new ANDA will be deemed a first applicant even if it later failed to comply with the statutory requirement that notice be provided within 20 days of FDA’s acknowledgement of receipt of the ANDA.” IVAX letter at 4, note 13. We disagree. As a matter of logic, Congress’s decision in the MMA to add a 20-day window for sending notice of a Paragraph IV certification in an original ANDA strongly supports Eon’s position, that the relevant priority date for 180-day exclusivity purposes for the sponsor of an original Paragraph IV ANDA (like Eon) is the date that a substantially complete original ANDA is first received by FDA. Under IVAX’s interpretation (where the priority date for an original Paragraph IV ANDA sponsor is the date when notice is actually sent), the MMA’s 20-day

window provision would be surplusage. Again, such an interpretation is disfavored and must be rejected. See Babbitt, 515 U.S. at 698.

While the MMA did not address what happens if an original Paragraph IV ANDA sponsor does not send timely notice within the 20-day window, it seems logical to assume (and for Congress to have assumed) that FDA would (through regulation or interpretation) adopt the same approach that it did for pre-MMA ANDA amendments to include a Paragraph IV certification to a newly listed patent: If the sponsor of a pending ANDA that is amended to include a new Paragraph IV certification failed to meet the statutory deadline (simultaneous notice for ANDA amendments under both prior law and the MMA), the sponsor would lose the benefit of its 180-day exclusivity priority date and would be “penalized” by getting, instead, a delayed priority date tied to the date on which it actually gave notice. This interpretation was upheld as reasonable by the D.C. Circuit in Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877, 888-89 (D.C. Cir. 2004).

But if FDA adopted IVAX’s approach, the 20-day window would serve no useful purpose, because an original Paragraph IV ANDA sponsor’s 180-day exclusivity priority date would be the date notice was sent, without regard for whether it complied with the statutory 20-day window requirement. Thus, IVAX is advocating an illogical interpretation. It is well-recognized in court decisions that illogical interpretations are not favored. See, e.g., Yankee Network v. FCC, 107 F.2d 212 (D.C. Cir. 1939) (“We cannot impute to Congress an intent to produce an absurd result”).

For these reasons, IVAX's petition should be denied.

Respectfully submitted,

/s/ Shashank Upadhye

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