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October 16, 2006

Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Re: Citizens Petition Regarding FDA Docket No. 01E-0213

To Whom It May Concern:

The undersigned submits this Citizens Petition under 35 U.S.C. § 156 and 21 C.F.R. Part 60 to request the Commissioner of Food and Drugs to deny the Request for Reconsideration of the date of approval of Angiomax ® and reaffirm that the approval date of the drug is December 15, 2000.

## I. ACTION REQUESTED

For the reasons outlined below, the undersigned respectfully requests that the Commissioner deny the Request for Reconsideration of the date of approval of Angiomax ® and reaffirm that the approval date of the drug is December 15, 2000.

## II. STATEMENT OF GROUNDS

### A. Background

U.S. Patent No. 5,196,404 to Maraganore et al. (the '404 patent) was issued on March 23, 1993. The claims of the '404 patent are drawn to a thrombin inhibitor which is the active ingredient of Angiomax ®. A New Drug Application (NDA) No. 20-873 for Angiomax was submitted on December 23, 1997 by The Medicines Company, exclusive licensee of the '404 patent. On December 15, 2000, the Medicines Company received an approval letter for this NDA by facsimile. The date stamped on this letter was December 15, 2000, and the signature block also clearly delineated that the approval was December 15, 2000.

A petition for patent term extension of the '404 patent was then filed with the U.S. Patent and Trademark Office (PTO) on February 14, 2001, 61 days after the date on the approval letter. Under 35 U.S.C. § 156(d)(1), however, an application for patent term extension must be filed within 60 days of the date of the approval of a product; thus, the application for a patent term extension was late. After correspondence between the PTO and FDA confirmed the approval

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date of Angiomax ®, the PTO therefore informed the applicant that the '404 patent was ineligible for patent term extension in a notice dated November 20, 2001.

### **B. The Request to Change the Approval Date Should Be Rejected**

On October 2, 2002, the applicant filed a Request for Reconsideration seeking to reverse the decision of the PTO to reject applicants patent term extension. The PTO forwarded the Request for Reconsideration to the FDA for assistance in answering the request in a letter dated March 24, 2003. According to the PTO's online file and subsequent phone inquiries with both agencies, no further action has been taken on this request since that date.

In the Request for Reconsideration, the applicant argues that, because the approval letter was signed by the FDA after normal business hours on December 15, 2000, the actual approval date of the drug should be considered December 18, 2000, the next business day. Further, the applicant argues that it would be inequitable to deny the patent term extension. Specifically, the applicant argues that, because the approval letter was signed at 5:18 p.m. on Friday, December 15, 2000 and was received by facsimile at 6:17 p.m. on that same date, the approval of the drug occurred after the close of normal FDA business hours (8 a.m. to 4:30 p.m.). Because of this, the applicant argues that the approval date of Angiomax should be considered to be Monday, December 18, 2000.

There are several compelling factual and legal reasons why applicant's Request for Reconsideration should be rejected.

First, the approval date of December 15, 2000 was expressly and clearly delineated both on the cover of the approval letter, as well as in the signature block. Indeed, there can be no serious dispute that applicant could have commenced shipping and/or selling its drug as of December 15, 2000, based upon the date of the letter. Further, the approval date of December 15, 2000 was also clearly listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

Applicant further argues that they were unable to issue a press release on the approval until Monday, December 18 and that faxes received by the FDA after close of business are viewed as received on the following business day. However, again, there is nothing to suggest that the applicant could not have acted on the approval letter on December 15, they simply chose not to. There does not appear to be any reason why the applicant could not have issued a press release on the evening of December 15 or even any reason why they could not have begun shipping the drug at that time.

Second, as a matter of policy, adopting the applicant's suggestion for the determination of approval dates would create a confusing and dangerous precedent. If the FDA were to inform a California company of the approval of its drug at 4:35 p.m. Eastern Time, it would be 1:35 p.m. Pacific Time. There is no reason to think that the FDA would prohibit the California company from issuing a press release regarding approval, despite the fact that the FDA issued the approval letter after its normal business hours.

Third, and most importantly, the issue at hand has **already been decided** by the U.S. Court of Appeal for the Federal Circuit. In *Unimed, Inc. v. Quigg*, a company filed for a patent term extension more than one year after FDA approval of their drug due to the mistaken belief

that they had 60 days from the reclassification of the drug by the Drug Enforcement Agency. *Unimed, Inc. v. Quigg*, 888 F.2d 826 (Fed. Cir. 1989). In denying the patent term extension, the Federal Circuit found the relevant statutory provisions (35 U.S.C. §§ 156(d) and 156(g)(1)(B)(ii)) to be clear and unambiguous and held that "we can find no implication that the approval date that commences the running of the sixty-day application period under subsection [35 U.S.C. § 156](d) should be different from the approval date that marks the end of the regulatory review period under subsection [35 U.S.C. § 156] (g)(1)(B)(ii)." *Unimed*, 888 F.2d at 829. As for what the approval date should be, the Federal Circuit stated, "[a]ccording to the FDA, **the date of marketing approval for all new drugs is the date appearing on its approval letters.**" *Unimed*, 888 F.2d at 828. (emphasis added). Accordingly, there is clear precedent from the Federal Circuit on how the patent term extension statute is to be interpreted. That court determined that the plain language of the statute precludes the result that the Medicines Company seeks. The undersigned respectfully submits that the issue as to which applicant is arguing is already well settled.

The applicant argues that the situation at hand can be distinguished from *Unimed*, but the only difference it suggests between the two situations is the amount of time by which the application for patent term extension was late. However, *Unimed* is a case of statutory interpretation, wherein the Federal Circuit held the statutory period to be 60 days and no more. The undersigned respectfully submits that the statute, already crystal clear on its face, has been clearly interpreted by the court, and that being late by one day is not distinguishable from being later by a longer period of time.

The applicant also argues that the approval date of Angiomax® should be considered to be December 18, 2000 because an approval date of December 19, 2000 was listed on the FDA's website for a period of time, likely as the result of a clerical error. The applicant argues that this posting caused confusion as to what the actual approval date was. However, in their original Application for Patent Term Extension the applicant clearly states, "[t]he date on which the approved product received permission for commercial marketing is 15 December 2000." Application for Patent Term Extension dated February 14, 2001, p.1. Thus, there does not appear to have been any confusion on the applicant's part at the time of the filing of that document. The undersigned respectfully submits that issue here is one of notice, and that the applicant had ample and clear notice of what the approval date was, because they acted as though they thought December 15, 2000 was the approval date of the drug.

The applicant also argues that it would be inequitable to deny the patent term extension of the '404 patent as part of their argument for changing the approval date of the drug. However, this issue was also clearly settled by the Federal Circuit in *Unimed*, where they stated, "this is purely a case of statutory interpretation, so the equitable considerations raised ... are inappropriate." *Unimed*, 888 F.2d at 829.

### III. CONCLUSION

The foregoing analysis demonstrates that applicant is simply seeking refuge from the FDA for its own internal mistakes and omissions in miscalculating the due date for its patent term extension application. However, the law cannot simply be manipulated and/or

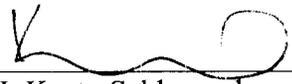
circumvented to suit applicant's needs, particularly where, as here, the facts, the law, and the policies underlying the relevant statutes are clear and unequivocal. Neither the FDA nor the PTO should be responsible for correcting a mistake that applicant – and only applicant – was responsible for. Therefore, the undersigned respectfully requests that the FDA deny the applicant's request to change the date of approval for Angiomax<sup>®</sup>, because the applicant had clear notice of what the approval date was, as shown by their actions and all relevant FDA sources, including the Orange Book and the approval letter itself. Further, the Federal Circuit has established a clear interpretation of the patent term extension statute, and the applicant's request is directly contrary to this law.

#### IV. ENVIRONMENTAL IMPACT

It is the belief of the undersigned that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, no environmental impact analysis is required.

#### V. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

  
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