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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Response to Banner Pharmacaps Inc.
Citizen Petition Docket No. 2005P-0436

The citizen petition filed by Banner Pharmacaps Inc. ("Banner") requests that FDA refuse to approve a Section 505(b)(2) application submitted by Ranbaxy Laboratories, Inc. ("Ranbaxy") for Ibuprofen Liquid Filled Gelatin Capsules 200 mg unless it contains a certification to the patent listed in the Orange Book for Banner's ibuprofen capsules 200 mg. On February 22, 2006, Ranbaxy submitted a response explaining why Banner's petition should be denied. Response to Banner Pharmacaps Inc., Docket No. 2005P-0436, Feb. 22, 2006 ("Ranbaxy Response"). On March 17, 2006, Banner submitted a supplement to its citizen petition, replying to Ranbaxy. Supplement to Citizen Petition, Docket No. 2005P-0436 (Mar. 15, 2006) ("Banner Supp."). On March 21, 2006, Banner submitted yet another supplement to its citizen petition, this time arguing that Ranbaxy's 505(b)(2) application should be converted to an ANDA. Second Supplement to Citizen Petition, Docket No. 2005P-0436 (Mar. 21, 2006) ("Banner Sec. Supp.").

Banner's citizen petition seeks to unduly and unjustifiably delay the approval of Ranbaxy's ibuprofen drug product. Ranbaxy is poised to launch its ibuprofen drug product following approval, which is anticipated on March 28, 2006. None of Banner's arguments justify delaying approval.

Banner Continues to Ignore the Plain Language of The Food, Drug, and Cosmetic Act

Banner's failure to address the governing statutory language in its initial petition, or in either of its two supplements, is both noteworthy and telling. Section 505(b)(2) of the Food, Drug, and Cosmetic Act ("FDCA") describes when a Section 505(b)(2) applicant must certify to the patents listed for a previously approved drug product.

An application submitted under paragraph (1) for a drug for which the investigations described in clause (A)... and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has

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not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include –

(A) a certification...with respect to each patent which claims the *drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)* –

21 U.S.C. § 355(b)(2) (emphasis added).

The statutory language clearly links the patent certification obligations to the listed drug on which the application relies. There is no ambiguity as to the patent certifications required in a 505 (b)(2) application. Where Congress so clearly expressed its intention on the precise question at issue, “that intention is the law and must be given effect.” New York v. EPA, F.3d (March 17, 2006), slip op at 9, quoting Chevron U.S.A., Inc. v. National Resources Defense Council, Inc., 467 U.S. 837 (1984). Ranbaxy’s 505(b)(2) application does not rely on any Banner drug product. Accordingly, it is not required to contain a certification to any Banner patent.

Banner asserts that, because Ranbaxy seeks approval of a product containing the same active ingredient as the active ingredient in Banner’s product, “Ranbaxy of necessity” is asking FDA to consider what is already known about the Banner drug product. Banner Supp. at 4. In making this argument, however, Banner is mischaracterizing the relevant statutory inquiry. Patent certification under Section 505(b)(2) is tied to the findings the applicant relies upon in the application – not to the findings FDA may have made in evaluating other applications.

Further, Banner’s “necessity” argument is not consistent with the way the FDA applies the FDCA more generally. When different applicants submit NDAs for the same active ingredient, FDA reviews those NDAs independently. It does not assume that it must of necessity apply its knowledge of one application to the other, and it does not require one applicant to reference the data of another applicant simply because the products involve the same active ingredient. The same principle should apply here.

Not only is Banner’s argument based on an improper reading of the Hatch Waxman provisions and inconsistent with the agency’s practice, but Banner’s proposed approach is also unworkable. There is no practical way to determine what FDA may already have learned in the context of other drug applications. Conditioning patent certifications on FDA’s familiarity with an active ingredient would leave applicants with no advance warning of what patent certifications must accompany an application. The resulting system inevitably would be arbitrary, unpredictable, and impossible to administer.

FDA's Fenofibrate Decision Does Not Support Banner's Argument

Banner argues that Ranbaxy ignored FDA's previous decision answering Abbott's Citizen Petition regarding fenofibrate and that this decision requires that Ranbaxy certify to the Banner patent. Banner Supp. at 1-3. In fact, the fenofibrate decision dealt with a different factual scenario. Moreover, the reasoning supporting the fenofibrate decision also supports Ranbaxy's position in this matter.

In responding to Abbott's citizen petition, FDA was answering a different question than the one presented here. There, FDA was considering whether the 505(b)(2) applicant, Reliant, was required to certify to patents contained in a second NDA on the same active ingredient from the same manufacturer. The second NDA had relied in part on investigations contained in the first NDA. Reliant had chosen to certify only to patents listed in the first NDA. In that situation, Reliant could have chosen either the first or second NDA as the applicable listed drug. In those circumstances, FDA concluded that Reliant was not required to certify to the patents in the second NDA, stating that it was not appropriate to require certifications to all future formulations relying on the same underlying investigation. Response to Citizen Petition of Abbott Laboratories, Docket No. 2004P-0386 (Nov. 30, 2004) ("Abbott Response") at 10.

The fenofibrate decision recognized that "[t]he language of section 505(b)(2) of the Act explicitly links the *drug* relied on for approval to the *drug* for which patent certifications must be made." Abbott Response at 6 (emphasis in original). Further, the decision explains that FDA's implementing regulations "reinforce this relationship between reliance and certification." *Id.* at 7. The analysis properly recognizes the linkage between reliance and certification.

Indeed, the fenofibrate decision appears to anticipate a similar situation to that at issue here. The decision hypothesized a situation in which two NDAs from the same sponsor were to have different patents listed, presumably because the patents listed for product B claim some aspect of product B – such as formulation or indication – that is not present in product A. FDA explained that an applicant that seeks to duplicate the aspect of product B that is not present in product A, and to rely on product B's approval to support this feature, will cite product B as its listed drug and must certify to the patents for product B. Conversely, an applicant that does not seek to duplicate that aspect of product B, and does not rely on findings for product B, "should be permitted to cite product A as its listed drug and certify only to the patents on product A." *Id.* at 8n.12. The same logic relied upon by FDA in the fenofibrate response compels the conclusion that Ranbaxy properly relied on the Wyeth NDA.

In this situation, Ranbaxy had far less reason to rely on the data in Banner's submission than Reliant had to rely on the data in Abbott's second NDA. The data Ranbaxy needed – on the safety and efficacy of ibuprofen for migraine – was not in Banner's application, but rather in Wyeth's application. In these circumstances, there is even less reason for FDA to require certification to Banner's patents than there was to require Reliant to certify to the patents in Abbott's second NDA.

The fenofibrate decision does refer to FDA's draft guidance, which states that a pharmaceutical equivalent of the proposed drug should be identified as the listed drug to ensure that the 505(b)(2) applicant does not use the 505(b)(2) process to "end-run" patent protections. *Id.* at 9. Even if such a policy were valid, itself a questionable proposition, Ranbaxy response at 5, it clearly has no applicability in this situation. Ranbaxy did not seek to end run any patent protections; it sought approval for a version of an ibuprofen product for migraines, which only Wyeth's data could support at the time Ranbaxy's application was submitted and reviewed.

Ranbaxy Cannot be Required to Convert its 505(b)(2) Application to an ANDA

In its most recent submission, Banner asserts that its ibuprofen product was approved for a migraine indication 10 days ago, and argues that this development precludes approval of Ranbaxy's 505(b)(2) application and requires that Ranbaxy convert its application to an ANDA and conduct additional studies. Banner Sec. Supp. at 2. In effect, Banner's position is that no one else should be allowed to do what Banner did – reference Wyeth's efficacy data without risking a patent litigation.

Ranbaxy knows of no circumstance in which FDA has compelled an applicant to change the statutory basis of its application following a decision to file the application, and knows of no policy or statement that suggests that FDA would ever consider such a step. Banner cites no law or precedent for its position.

Further, adoption of Banner's approach inevitably would result in an unmanageable administrative burden and enormous waste of resources. Neither an applicant nor FDA can predict in advance whether an approved NDA holder will request approval for an additional indication or whether such an application will be approved. If FDA were to adopt Banner's approach, both the applicant and FDA would expend resources in submitting and reviewing a properly filed application, only to have to start again at the very last minute. Banner's approach would not only be wasteful, but manifestly unfair to an applicant that, through no fault of its own, would have to begin the application process again. And it would be unfair to the public, which would be denied the opportunity to choose from among competing drugs, while the applicant reconfigured, and FDA re-reviewed, the application.

Even if FDA were inclined to adopt Banner's approach, it has no statutory authority to do so. Both the words and the structure of § 505 of the FDCA compel the conclusion that (except for issues of exclusivity, which are not relevant here) FDA lacks authority to refuse to file, review, and approve a new drug application under § 505(b)(2) merely because it has previously approved another new drug application. Section 505(a) provides that a new drug may not be lawfully marketed unless it is the subject of either approved New Drug Application under § 505(b) or an approved Abbreviated New Drug Application under § 505(j). Either an NDA or an ANDA is permissible; the statute expresses no preference. That the choice of an NDA or an ANDA is the applicant's is reinforced by the wording of §§ 505(b) and 505(j). "Any person" may submit an NDA under § 505(b), and "any person" may submit an ANDA under § 505(j). The statute imposes no duty on "any person" to refrain from submitting an NDA if an ANDA is also a possibility; the choice is left up to the applicant.

This interpretation is reinforced by the language of the statute regarding denials of applications. The FDCA does not make FDA's approval of a previous NDA a ground for denial of a later NDA submitted under § 505(b). If an NDA is submitted under § 505(b), FDA must (after a specified time period) approve it unless it finds that one or more of the grounds specified in § 505(d) is applicable. FDCA § 505(c). None of the grounds in § 505(d) has anything to do with whether one or more applications for the same drug were previously approved under § 505(b)(2), an omission which is fatal to Banner's claim that FDA should refuse to approve Ranbaxy's NDA on the ground that it had previously approved another NDA for a product containing the same active ingredient.¹

The approval of a migraine indication for Banner's drug product at this late date is irrelevant as a matter of law in determining whether the Ranbaxy application was complete, appropriately filed and may now be approved. At the time Ranbaxy submitted its application, there were no findings on which Ranbaxy, or FDA, could rely upon as to the efficacy of the Banner drug in the treatment of migraine. Because Ranbaxy has complied with all the applicable statutory and regulatory criteria, it is entitled approval. No authority permits, let alone requires, the conversion of Ranbaxy's 505(b)(2) application to an ANDA or the denial of a 505(b)(2) on this basis.

1. Even if FDA could compel an applicant to submit its application under section 505(j), the time to do so has long since passed here. FDA's regulations provide that the appropriate time for notifying an applicant that it would prefer an ANDA to a 505(b)(2) application is at the time the application is reviewed for filing. 21 C.F.R. 314 § 101(d)(9).

Banner's Approach is Contrary to the Goals of Hatch Waxman

Banner's assertion that Ranbaxy engaged in gamesmanship to avoid certification to Banner's product is as reckless as it is wrong. Banner Supp. at 4. Ranbaxy's 505(b)(2) application complies with all of the statutory and regulatory criteria for approval of a version of the Wyeth migraine drug product. Banner, on the other hand, having availed itself of the same statutory pathway to gain approval for its drug product, now seeks to foreclose it to all others. Such a result would award Banner market power that far exceeds any reasonable expectation, in derogation of the intent and express language of Hatch Waxman. While there are statutory provisions in the FDCA that allow the first applicant to obtain approval to earn exclusivity or prevent others from utilizing the same pathway for approval for a limited period of time, see Sections §§ 505(e) and 527, Banner has not availed itself of any of these and, therefore, can claim no right to foreclose Ranbaxy, or others, from pursuing a 505(b)(2) application.

Conclusion

As a factual matter it is undisputed that Ranbaxy's 505(b)(2) application does not rely on the approval of Banner's drug product. Banner cannot and does not argue otherwise. Nor does Banner dispute that Ranbaxy's 505(b)(2) application filled the gap between the Wyeth migraine product and Ranbaxy's proposed drug product by supplying its own data. Having met the statutory and regulatory criteria, Ranbaxy is entitled to approval.

Very truly yours,



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