Compton, Kimberly

From: Compton, Kimberly
Sent: Tuesday, June 09, 2009 6:04 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: RE: NDA 22-266 - Review Status and Action Timings
Attachments: Onsolis mg june 9 09 medication guide .doc

Hi Dave,

I have reserved the only slot left on Dr. Hertz calendar on Friday for us to talk. That slot is at noon-12:30 and so we will plan to call BDSI with a status update at that time. Should we use the usual call in number?

The attendees on our call today were Sharon Hertz, Ellen Fields, Mary Willy, Twyla Thompson, Brian Gordon, Afrouz Nayernama, Agnes Plante, and myself.

I have shared your clarification provided below with Drs. Rappaport and Hertz.

Attached is a copy of the MG with two suggested revisions intended to clarify the website information listed in the MG. The changes are tracked so you should be able to easily see them, but on is in the "How Should I Use Onsolis" section and the other is at the end of the MG. OSE's MG experts recommended these small changes to improve understanding of the website info in the MG. Please let me know if BDSI agrees to incorporate these changes into the MG.

We hope to provide the website information in the next day or so.

Thanks
Kim

From: David T. Wright [mailto:DTWright@bdsinternational.com]
Sent: Tuesday, June 09, 2009 5:30 PM
To: Compton, Kimberly
Cc: Andrew Finn; Mark Sirgo; rspivey@medapharma.us
Subject: NDA 22-266 - Review Status and Action Timings

Kim:

Thank you for pulling your team together for today's teleconference. Please send a list of the Agency attendee names when convenient. The sponsor attendees were Dr Mark Sirgo, President and CEO, BDSI; Dr Andrew Finn, Executive VP, Product Development, BDSI; Dr Richard Spivey, Chief Scientific Officer, Meda Group (commercial partner for ONSOLIS); and myself.

We look forward to feedback later today regarding the website address on page 27 of the Medication Guide for ONSOLIS.

We also look forward to receiving agreement or further comments on the Website Educational Materials within the next 1 to 2 days.

Would you like to schedule time for the next teleconference that Dr Hertz mentioned during the call today? If so, anytime Thursday afternoon (BDSI's preference) or Friday morning works for us.

Acknowledging the sensitive nature of this topic and to clarify our position, in the event that the pending action cannot be completed this Friday, BDSI requests an action delay rather than a Review Extension Letter. As indicated previously, a 3-month review extension will have a potentially negative impact on BDSI. In our teleconference on 21 May, the Agency review team agreed to the content of all REMS materials with the single exception of the Website Educational Materials (website). Comments on the website were received on 04 June and a revised website, addressing all Agency comments, was sent via email on 05 June. Thus, it is BDSI's position that the formal gateway submission of our agreed REMS materials does not constitute a "major amendment to a pending application", defined in MAPP 6010.8 as "An amendment to a pending application that contains one or both of the following:

1) a substantial amount of new data or new information not previously submitted to, or reviewed by, the FDA (e.g., a major new clinical safety or efficacy study report, a proposed Risk Evaluation and Mitigation Strategy), or
2) a new analysis or major reanalysis of studies previously submitted to the pending application."

Further, our proposed REMS submitted on 12DEC2008 as a response to your Complete Response letter initiated a 6-month resubmission review clock. BDSI believes that all NDA amendments during this review cycle have been minor amendments to provide clarifications or other minor textual revisions to address FDA review comments rather than strategic or operational changes to the REMS.

We certainly do not want this to be a contentious issue particularly given the fact that you are so close to an action. However, given the significance of this point to BDSI, we just wanted to clarify our position. As always, I am sure we can work through this topic in the next few days.

We appreciate all of the effort that you and your team are putting into reaching a prompt action on our application resubmission.

Best regards, Dave

David T Wright, PhD, RAC
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8 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kimberly Compton
6/9/2009 06:25:48 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Thursday, June 04, 2009 4:35 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: REMS comments and responses to your questions

HI Dave,

In response to your questions from yesterday, below are our replies.

1. Website Educational Materials – Will BDSI receive the pending Agency comments later today? These are provided below.

2. All other REMS materials – Are these materials agreed or will BDSI receive further Agency comments? If there are further comments, when will BDSI receive such comments? A few additional REMS comments are provided below along with the web comments; otherwise the Division does feel we have agreement on the other REMS materials. However, we must point out that these materials must still undergo final review by other groups in the Agency (outside of the review team) and it is always possible they will recommend changes to the agreed-upon materials. While we do not anticipate additional changes, it is always possible. We would convey any recommended changes as soon as we received them but do not have an estimate of when that might be.

3. All other NDA documents, including the PI/MG for ONSOLIS – Are these documents agreed or will BDSI receive further Agency comments? If there are further comments, when will BDSI receive such comments? Similar to the situation in Number 2 above, the Division does feel we have agreement on the labeling materials. However, we must point out that these materials as well must still undergo final review by other groups in the Agency (outside of the review team) and it is always possible they will recommend changes to the agreed-upon materials. Again,while we do not anticipate additional changes, it is always possible. We would convey any recommended changes as soon as we received them but do not have an estimate of when that might be.

4. Container and carton labeling – Is it possible for BDSI to receive final approval of these labels to minimize delays between NDA approval and product launch? If so, when will BDSI receive such approval? You indicate in your summary of the recent May 29 meeting with the Division which you provided in your email yesterday that approval for carton and container labeling could be provided prior to NDA approval:

   > When asked if the Agency could approve the ONSOLIS container and carton labeling now to minimize the time between NDA approval and product launch, Dr Hertz stated that this was possible and that she would determine how to accomplish this soon.

   However, we must point out, as we have previously, that (although we do not anticipate this), it is always possible that when the application materials undergo final review, additional changes may be recommended and so while we have indicated that these pieces are currently acceptable as proposed, we have no mechanism to provide early approval or official clearance of them prior to approval of the application. We apologize if that was unclear in our meeting discussions.

Below, please see our remaining additional comments on the REMS program materials. These mainly deal with the draft web materials sent by email on May 26, but include a few other minor points/clarifications as well.

1. We were unable to follow the links on the webpage (as it is not live) to the linked educational pieces so could not confirm that the enrollment forms on the website were updated to reflect changes we'd previously agreed upon. Please confirm this.

2. Ensure that the website address is consistent throughout all the literature/material for Onsolis.

3. Page 20 of the web shot from the May 26, 2009 email submission states:

b(4)

b(4

4. Add a "d" in front of "none of these apply" to Question 1 on the Prescriber KAB survey.

5. Change ———— to "pharmacies" on Form FF 16 as indicated below: b(4)

   The FOCUS™ Program for ONSOLIS™ requires that ———— re-enroll every 2 years. Your enrollment period will end on MM-DD-YYYY. b(4)

6. b(4)

7. Please let us know if you have begun printing of the FAQ document.

We still continue to work as hard as we are able to finalize this application and provide you with as timely feedback and accurate information as soon as it is known to us.

Thanks
Kim

Kimberly Compton
Kimberly Compton, R.Ph.
Regulatory Project Manager
Division of Anesthesia, Analgesia and

Rheumatology Products (HFD-170)
301-796-1191

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kimberly Compton
6/4/2009 04:38:44 PM
CSO