Compton, Kimberly

From: Compton, Kimberly
Sent: Wednesday, February 25, 2009 6:17 PM
To: 'David T. Wright'
Subject: today's update on Onsolis Rvw

Hi Dave,

The team had a few more things for Onsolis come up today and I wanted to send them right off to you. They are not really big and do not really require any work on BDSI's part, but I wanted to keep you as up to date with what's going on as possible like I promised.

The 1st is a reply regarding one of the questions in your 1-26-09 email-

1. REMS General – BDSI is aware of and has been approached [redacted] b(4)

   Dr. Hertz discussed this question with the appropriate folks internally and we can now offer the following position which we hope will help BDSI understand the perspective from which we are reviewing the Onsolis REMS:

   > The Agency is conducting a review of BDSI's proposed REMS for Onsolis and if we can reach agreement about this program we plan to be able to take an approval action.

The second item is regarding BDSI's request for early agreement or feedback on portions of the carton and container labeling-

> While we have discussed this issue in the past and we have previously reminded BDSI that until final approval is granted, any portion of the application would still be subject to changes, should the team feel they were necessary; however, as we have undertaken this collaborative review process with OSE, DDMAC, and CSS, it has become even more apparent that this will hold true given the novel aspects of the REMS review process and the mere existence of REMS for the product—still a fairly unique item in the marketplace.
>
> We therefore need to emphasize that the REMS review is a dynamic process and, as all the pieces of the REMS are inter-dependent on one another, as one is changes, it may have impact on others. So we feel it is important to emphasize that while we will provide feedback on all aspects of the REMS, including the carton and container labeling, as it becomes available to us, nothing should be considered final until the approval letter is signed.

I hope this information is useful and will continue to convey items as they arise.

Thanks,
Kim

Kimberly Compton

Kimberly Compton, R.Ph.
Regulatory Project Manager
Division of Anesthesia, Analgesia and
Rheumatology Products (HFD-170)
301-796-1191

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/s/

Kimberly Compton
4/8/2009 05:40:17 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Monday, March 16, 2009 7:32 PM
To: 'David T. Wright'
Cc: Stradley, Sara
Subject: PI and MG revisions for Onsolis

Attachments: N 22-266 PI w props'd chngs by firm 12-12-08--USE FOR EDITS.doc

HI Dave,

Attached please find a marked-up copy (showing both BDSI's proposed changes and the Agency's changes for this cycle) of the PI and MG for Onsolis.

N 22-266 PI w props'd chngs by...

Please review this material with your team and let us know if BDSI can agree to the changes we have proposed.

If not, please send us by return email attmt (please make sure to copy my supervisor, Sara Stradley as I will be on leave starting Mar 18 thru the 30th) a counter proposal clearly showing BDSI's NEW changes. You do not need to submit this counter proposal formally at this time as negotiations are still underway. Once we've reached final agreement on the PI and MG, then you may send us a formal amendment to the NDA.

In addition, please send us a mock-up of your carton label as soon as possible so the team may complete their reviews of all the labeling for this product.

Thanks,
Kim

Kimberly Compton
Kimberly Compton, R.Ph.
Regulatory Project Manager
Division of Anesthesia, Analgesia and
Rheumatology Products (HFD-170)
301-796-1191

34 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Kimberly Compton
4/8/2009 05:40:06 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Monday, February 02, 2009 4:42 PM
To: 'David T. Wright'
Subject: RE: NDA 22-266 for ONSOLIS

HI Dave,

I discussed this with Sharon Hertz, who as you may know is functioning in both her everyday role of the Deputy Division Director for this group of products (opioids) as well as the Cross-Discipline Team Leader (CDTL) for this application. She asked me to thank BDSI for the email, but noted that we have not confirmed our internal schedule for the review of this submission. However, as always, we will provide BDSI with additional information as it becomes available and is cleared for release. We do not believe that a telecon is necessary at this time.

I will remind the team that BDSI is anxious for feedback on the container labeling, but in any case, as we may have discussed, until the application is approved, any advice on the labeling would be considered tentative/preliminary and would be subject to change and/or final clearance by the signatory authority, etc., so even if we were able to provide the feedback BDSI is looking for, it would still be a business decision on BDSI's part if the risk of the Agency's advice changing balanced the benefit to preparing the labeling in advance of a final action.

We greatly appreciate BDSI's commitment to the review of this application.

Thanks,
Kim

From: David T. Wright [mailto:DTWright@bdsinternational.com]
Sent: Monday, February 02, 2009 3:48 PM
To: Compton, Kimberly
Subject: RE: NDA 22-266 for ONSOLIS

Kim:

Thank you for your prompt response to Questions 2 and 3 of my pervious e-mail. BDSI is encouraged that our proposed REMS is being actively reviewed and we look forward to Agency feedback shortly.

Regarding the proposed REMS, BDSI believes that our submission meets the Agency requirements specified in the Complete Response Letter and discussed during the November End of Review meeting. If the Agency identifies significant changes in the requirements for our REMS, BDSI would greatly appreciate feedback as early as possible in this review cycle so that we have an opportunity to appropriately modify and submit expeditiously.

Based on our September teleconference and November meeting with the Agency, it is our understanding that we will be working together to reach agreement on the REMS during this review cycle. Using the review timeframe described in your email, can we assume the following approximate schedule of review events:

1. End February – feedback on the REMS elements to assure safe use,
2. End March – feedback on the complete REMS,

3. End April – agreement on the complete REMS, and
4. Early to mid May – labeling comments?

If the Agency does not agree with this general timetable, BDSI would like to schedule a teleconference as soon as possible so that we have a common understanding of timelines for review and comments and the overall involvement of BDSI in the process.

Regarding the proposed labeling, as discussed during our End of Review meeting, BDSI would greatly appreciate earlier feedback related to the container labeling (not necessarily the carton labeling).

Please note that BDSI continues to be committed to providing rapid responses to the Agency to avoid additional delays and expedite approval of our application.

Best regards, Dave

David T Wright, PhD, RAC
Director, Regulatory Affairs
BioDelivery Sciences International (BDSI)
801 Corporate Center Drive, Suite 210
Raleigh, NC 27607

T: 919.582.9050
F: 919.582.9051

From: Compton, Kimberly [mailto:kimberly.compton@fda.hhs.gov]
Sent: Wednesday, January 28, 2009 2:18 PM
To: David T. Wright
Subject: RE: NDA 22-266 for ONSOLIS

Hi Dave,

I did enjoy the break as well, but agree it already seems so far removed. I am glad you enjoyed your time off as well.

I wanted to let you know that the team has been working to come up with answers to your below questions. I have some info I can share now and that is below the rest, we are still discussing and I will send once we have resolution on this end.

> Regarding the REMS Review –the submission is under review by the team (equal parts DAARP and OSE with DDMAC working on it as well. We have team meetings at regular intervals on the calendar to discuss the review over time but have no specific feedback for BDSI at this time.
>
> Regarding the labeling Review –similarly, we have no comments on the labeling at this time. We hope to have comments for BDSI in early to mid May.
>
> Regarding our availability for a TC, as we have no feedback to provide at this time, we hope this email will be sufficient and will reserve the TC for a time when we may have feedback to provide.

Thanks
Kim

From: David T. Wright [mailto:DTWright@bdsinternational.com]
Sent: Monday, January 26, 2009 5:43 PM
To: Compton, Kimberly
Subject: NDA 22-266 for ONSOLIS

Kim:

Happy New Year!! I hope you enjoyed your time off over the holidays. Mine was enjoyable but already seems like a distant memory.

I just left you a voicemail requesting a brief teleconference with you to discuss the following topics but wanted to follow it up with an email for your convenience:

1. REMS General – BDSI is aware of and has been approached by at least 2 consortiums which are trying to establish a common REMS for high potency opioids. BDSI is not currently interested in joining one of these consortiums as we already have a proposed REMS under review. What is the Agency view of these consortiums? Is there any chance these consortiums could impact the review of the proposed ONSOLIS REMS?
2. REMS Review – How is the review of our proposed REMS going? Are OND and OSE working through the new REMS review procedures? Do you have any timeline for review milestones? When can BDSI expect to receive feedback?
3. Labeling Review – How is the review of our proposed labeling going? Do you have any timeline for review milestones? When can BDSI expect to receive feedback?

Please let me know your availability to hold this brief teleconference.

In addition, is there a day and time when it is most convenient for me to call you with these types of questions?

Thanks in advance!

Best regards, Dave

David T Wright, PhD, RAC
Director, Regulatory Affairs
BioDelivery Sciences International (BDSI)
801 Corporate Center Drive, Suite 210
Raleigh, NC 27607

T: 919.582.9050
F: 919.582.9051

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/s/

Kimberly Compton
4/8/2009 05:36:42 PM
CSO