Compton, Kimberly

From: Compton, Kimberly
Sent: Monday, July 13, 2009 1:46 PM
To: 'David T. Wright'
Cc: Stradley, Sara; Hertz, Sharon H
Subject: FW: question on REMS document
Attachments: ONSOLIS REMS 7 13 09 OCC final.revised.doc

HI Dave,

Attached is our revised version of the REMS that we think can be the final version if BDSI agrees to all changes. Regarding your earlier question about BDSI vs Contractor being listed, we understand your point, however, in terms of the REMS, for the Patient Enrollment form, we cannot simply say " [redacted] without stating to whom the agency relationship belongs, so we would propose saying something like "BDSI (sponsor)/Meda Pharmaceuticals (licensee) and their agents contractors" so that we clarify for patients, but maintain the clarity needed. Would that work? We have proposed that on page 8 that we hope is acceptable to BDSI as it is OK with our legal folks on this end.

If this is all OK with BDSI, please go ahead and work to submit the gateway version of this and all the finalized supporting materials so we can wrap this up.

Please let us know if any problems, questions, etc. Please continue to copy Sara as my availability today is intermittent.

Thanks
Kim

From: David T. Wright [mailto:DTWright@bdsinternational.com]
Sent: Monday, July 13, 2009 11:22 AM
To: Stradley, Sara
Cc: Compton, Kimberly; Andrew Finn; Mark Sirgo; rspivey@medapharma.us
Subject: RE: question on REMS document

Sara:

Now, I have a question to ask. On page 8 of the REMS I sent last Friday, according to a comment from the Agency on the Patient Enrollment Form, the patient is required to acknowledge that:

...

[redacted] b(4)

Is it OK with the Agency for us to revise "[redacted]" in the above statement to "[redacted]" b(4)

[redacted] Please note that our commercial partner, Meda Pharmaceuticals, will be implementing the REMS and as such BDSI is not mentioned in the REMS enrollment forms to prevent confusion for patients and prescribers in understanding the relationship between BDSI and Meda. b(4)

Thanks in advance for your assistance!

Best regards, Dave

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

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F: 919.582.9051

From: David T. Wright
Sent: Monday, July 13, 2009 10:05 AM
To: 'Stradley, Sara'
Cc: Compton, Kimberly; Andrew Finn; Mark Sirgo; Rich Spivey (rspivey@medapharma.us)
Subject: RE: question on REMS document

Sara:

Thanks for your question. Yes, the same program overview will be used for both prescribers and pharmacists. We have now renamed this "Healthcare Professional Program Overview" in all applicable REMS materials to distinguish it from the "Patient Program Overview". Please let me know if you have any further questions.

Best regards, Dave

David T Wright, PhD, RAC
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From: Stradley, Sara [mailto:Sara.Stradley@fda.hhs.gov]
Sent: Monday, July 13, 2009 9:57 AM
To: David T. Wright
Cc: Compton, Kimberly; Stradley, Sara
Subject: question on REMS document

Hi Dave
We are reviewing the REMS that was sent on FRI. We have one question that needs clarification: on page 7 section f.i. is the "program overview" that is listed the same as the "prescriber program overview"? I am covering for Kim this morning.

Thanks

Sara E. Stradley, MS
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/s/

Kimberly Compton
7/15/2009 03:00:41 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Thursday, July 09, 2009 7:11 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: Onsolis REMS

Attachments: ONSOLIS REMS 7.9.09 final track.doc

HI Dave,

Today we got back a tracked version of the REMS for Onsolis from the team in OCC who has been reviewing it. A copy is attached. Please look over the changes, let us know if you have any questions, etc., but if BDSI is amenable to the changes, please make them in the document, make all the companion documents or documents that refer to this one agree, and send us the updated version of them all as soon as you can.

ONSOLIS REMS
7.9.09 final trac...

Please let me know if any questions.

Thanks
Kim

Kimberly Compton
Kimberly Compton, R.Ph.
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/s/

Kimberly Compton
7/10/2009 01:57:46 PM
CSO