

Compton, Kimberly

From: Compton, Kimberly
Sent: Thursday, May 21, 2009 2:09 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: comments and a few revisions for ONSOLIS REMS

Attachments: _____, -FDA edits 21MAY2009.doc; Dear Pharmacist Letter - FDA edits 21MAY2009.doc; Dear Prescriber Letter - FDA edits 21MAY2009.doc; ONSOLIS REMS - FDA edits 21MAY2009.doc

b(4)

Hi Dave,

I know it is very late notice, but wanted to send along before our TC this afternoon a few points/requests that the team has just sent to me:

1. Our concerns regarding the educational materials and enrollment forms have been addressed.
2. The KAB survey concerns have been addressed.
3. Regarding the _____, Website, and the _____ the word "Focus" is still in the website address. Clarify if the address will be "onsolisfocus.com" or if "Focus" be removed from the name.
4. In the REMS Supporting Document and forms FF11-13, an _____ is mentioned. Submit a copy of the _____ intended for the prescriber, pharmacy and distributor that explains what kind of response is expected from the non-compliant person(s).

b(4)

In addition, I have attached an edited version of both the Dear Pharmacist and Dear Prescriber Letters, _____ and the REMS (they each have very small edits only). I have accepted the changes we are OK with and just left the changes we had tracked. I hope that makes it easier to finalize them.



-FDA edits 21...



Dear Pharmacist
Letter - FDA e...



Dear Prescriber
Letter - FDA e...



ONSOLIS REMS -
FDA edits 21MAY...

As we are still working on this material, we may have additional comments in our TC this afternoon, but we thought these could be sent along now.

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)

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_____ Deliberative Process (b5)

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/s/

Kimberly Compton
5/21/2009 02:28:59 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Friday, May 15, 2009 6:58 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: Comments on ONSOLIS REMS referenced during 5-14-09 TC

Attachments: Onsolis REMS comments 5-14-09.doc

Hi Dave,

As promised, attached are our additional comments on the Onsolis REMS that we said we would send along by email today.



Onsolis REMS
omments 5-14-09...

Please let me know if you have any questions, etc.

Have a nice weekend,
Kim

Kimberly Compton
Kimberly Compton, R.Ph.
Regulatory Project Manager
Division of Anesthesia, Analgesia and
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The below comments pertain to the following ONSOLIS REMS materials:

- Proposed Educational material dated: dated April 30, 2009
 - Educational Materials for Prescribers and Pharmacists (formerly _____) b(4)
 - Program Overview (now included in the training material)
 - Prescriber Enrollment Form
 - Patient Enrollment Form
 - Wholesaler Enrollment Form
 - Pharmacy Enrollment Form
- Revised REMS and Supporting document: dated May 11, 2009
- Revised KAB survey (patient and prescribe surveys): dated May 11, 2009

These comments are in addition to the issues discussed in our May 14, 2009 TC. The discussed issues should also be addressed as agreed upon during that call.

1. Comments on Educational Materials for Prescribers and Pharmacists document

a. Remove the promotional statement “_____ from the *Dosing and Administration/Appropriate Product Dosing and Administration* section. The safety of patients using such products is dependent on healthcare professionals prescribing them in strict conformity with their approved labeling with respect to patient selection, dosing and proper conditions for use. b(4)

b. Delete the following statement from the *Risks of ONSOLIS/Overdose* section. _____ b(4)

2. Comments on the Prescriber and Patient Surveys

a. The REMS Supporting Document section 6.6.1.3 Survey Conduct (pg 44) states _____ and the Patient and Physician KAB surveys state _____

Clarify the number of follow-up phone calls that will be made to participants that do not return the survey. (Note: _____ If that is the case, then delete the statement from the REMS Supporting Document.) b(4)

b. Explain the reason for decreasing the sample size from 325 to 82.

c. On the Patient Survey, move the demographic questions (Questions 6-10) to the end of the survey.

- d. On the Physician Survey, consider the option of allowing physicians to fax the completed survey and receive feedback by fax.

3. Comments on the REMS and REMS Supporting Document

- a. On page 5 of the REMS, at the end of Section 1 on Healthcare Providers who prescribe ON SOLIS are educated and enrolled in the FOCUS Program add,

BioDelivery Sciences International, Inc. will monitor prescribers' education and certification requirements and may de-activate noncompliant prescribers until the requirements are met.

- b. ~~Page~~ 10 of REMS, substitute the following for the Implementation System.

- i. BioDelivery Sciences International, Inc. will maintain a database of certified entities to monitor and evaluate implementation of the elements provided for under Elements to Assure Safe Use, above.
- ii. BioDelivery Sciences International, Inc. will monitor the distribution of Onsolis to ensure that the drug is only shipped to certified pharmacies and will institute corrective actions if non-compliance is found.
- iii. BioDelivery Sciences International, Inc. will monitor the dispensing of Onsolis by certified pharmacies to ensure only enrolled and authorized patients are receiving Onsolis and only certified prescribers are prescribing Onsolis. If a dispensing entity is found to be non-compliant with the Onsolis REMS, BioDelivery Sciences International, Inc. will institute corrective actions.
- iv. BioDelivery Sciences International, Inc. will monitor, audit, and evaluate all certified pharmacies, distributors, and the REMS FOCUS PROGRAM at the initiation of the REMS program to ensure they implement the program as directed.
- v. BioDelivery Sciences International, Inc. will monitor and evaluate the elements to assure safe use in the manner described in the REMS Supporting Document, and take reasonable steps to work to improve implementation of these elements.

- c. On page 11 of the REMS, modify the language ' _____

b(4)

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment time interval. The assessment is to be received by the FDA on the due date.

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/s/

Kimberly Compton
5/15/2009 07:21:40 PM
CSO

Compton, Kimberly

From: Compton, Kimberly
Sent: Monday, May 04, 2009 7:26 PM
To: 'David T. Wright'
Cc: Compton, Kimberly
Subject: Comments on REMS Supporting Document for Onsolis (Section 6.4.3.1)
Attachments: N 22-266 REMS SD cmmts 6.4.3.1 5-4-09.doc

Hi Dave,

Attached please find a marked up copy of the REMS supporting document section 6.4.3.1. It contains embedded comments/notes as well.



N 22-266 REMS SD
cmmts 6.4.3.1...

Please let me or Sara know if you have any questions.

Thanks
Kim

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

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/s/

Kimberly Compton
5/4/2009 07:50:21 PM
CSO