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Subject: BL 125646 REMS IR
Date: Wednesday, August 23, 2017 11:50:00 AM
Attachments: [FDA revised 08.22.17.rems-hospital-cert-form.pdf](#)
[FDA revised v2 08.22.17.rems-wallet-card.pdf](#)
[FDA revised 08.22.17.rems-website.pdf](#)
[image001.png](#)

Good afternoon,

Please see the information request below and the attached documents and provide a response by 4 pm on August 25, 2017. Please send a response directly to this e-mail and follow-up by providing the information as an official amendment to the BLA.

We are editing the REMS and REMS Supporting documents and will have a version to you soon. In the meantime, we have edits for:

Hospital Enrollment Form:

We recommend removing some content that is not necessary on the form about REMS goals, as well highlighting the information about how to return the form. These changes will allow the form to be less cluttered and improve readability.

Patient Wallet Card:

We have made substantial recommendations to the Patient/Caregiver Wallet Card. In an effort to keep the revisions clear, we have completely deleted some text, instead of putting a red line through it. In addition, our added text may not always be noted as new, in order to show you what the layout of the card would look like.

The patient information should be clearly laid out with a heading that identifies the information as such. Include a heading that says "Patient Information" on the back of the card.

The signs and symptoms listed should only be the ones that are severe and life-threatening, per the Medication Guide. Delete the additional signs and symptoms. There also needs to be a statement that identifies these signs and symptoms as severe and life threatening. Increase the font size of the action statement in red for the patients. The message for patients to stay within 2 hours of a Kymriah treatment site for at least 3-4 weeks should also be moved to be with other messaging that is for the patient.

The Healthcare Provider side of the card needs to be reorganized. The risk information on CRS should be upfront. The indication can be moved down below the fold of the card. The following statement is for the patient and can be removed from the HCP side of the card, "Patients and their caregivers should plan to say within 2 hours of a Kymriah treatment site for at least 3 to 4 weeks after receiving Kymriah treatment, unless otherwise indicated by the doctor." Include an exclamation point or similar graphic next to the CRS risk information to indicate this is important information. In focus group testing with emergency personnel, participants have stated that symbols like these that are common in emergency department settings, indicate important information that can be located quickly.

REMS Website:

Remove the two references to the stand-alone Kymriah REMS CRS Management Algorithm at the bottom of the landing page.

Please confirm receipt of this request.

Thank you,

Erica Giordano

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