From: Giordano, Erica
To: Patel, Manisha (manisha.patel@novartis.com)
Cc: Riggins, Cindy; narin.ahmed@novartis.com
Subject: BL 125646 REMS Information Request
Date: Wednesday, August 16, 2017 2:00:46 PM
Attachments: image001.png
Kymriah REMS Supporting Document v3.0_Clean 09 Aug2017.docx
Kymriah REMS Document v3.0 Clean 07Aug2017.docx
Draft REMS Assessment Plan for Kymriah (3).docx

Good afternoon,

Please see the information request below and the attached documents and provide a response by 4 pm on August 18, 2017.

1. Provide comments and edits to both the REMS document and the REMS supporting document
    a. In the REMS supporting document, modify the REMS assessment Plan (section 5) to be aligned with the attached assessment plan document.

2. All REMS materials (REMS training slides, REMS Knowledge Assessment, REMS Program Hospital Enrollment Form, REMS Website, and Patient/Caregiver Wallet card) must be revised to be consistent with the final FDA approved labeling and REMS Document and resubmitted for review.
    a. FDA is unable to determine the ease of usability of the materials until we see the actual layout and formatting of the material (specifically the REMS Hospital Enrollment Form and the REMS Knowledge Assessment). Submit REMS communications materials as .PDF files if appropriate to show the appropriate layout, formatting and design, including actual font colors and font size, and Kymriah and Novartis logo additions. For example, the wallet card design should show the actual size of the card, if it was to be folded, printed front and back and any symbols or graphics.

3. REMS letter to Healthcare Providers and REMS Factsheet
    a. Since the REMS is no longer a communication plan, the proposed REMS letter to Healthcare providers and REMS factsheet does not need to be included as part of the REMS and can be removed.

4. CRS Management Algorithm
    a. You provide the CRS Management Algorithm as part of your REMS training slides. Since it is included in the REMS training slides, and this information will be included in labeling, it does not need to be included as a separate document as part of the REMS, therefore we removed it.

5. Patient/Caregiver Wallet Card
    a. The information on the wallet card should contain patient-friendly language consistent with the Medication Guide as appropriate, bullets, as well as colors (e.g., red, yellow and black), symbols or graphics (e.g., warning symbols) and bold fonts as necessary so that emergency department personnel and other healthcare providers recognize the importance of the information, urgency of action and need to contact the treating oncologist, and the need for the patient to stay within 2 hours of the Kymriah treatment

site for 3-4 weeks. The risk of CRS and neurotoxicity should be clearly laid out for the healthcare providers, along with any actions that should be taken if a patient presents the card in a hospital setting.

Please confirm receipt of this request.

Thank you,

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