

From: Khurana, Taruna

Sent: Friday, January 31, 2020 8:47 AM

To: Louise Peacock <lpeacock@aimmune.com>; 'wturner@aimmune.com' <wturner@aimmune.com>

Cc: ClarodaSilva, Tatiana <Tatiana.ClarodaSilva@fda.hhs.gov>; Oram, Diana <Diana.Oram@fda.hhs.gov>; Wang, Qun <Qun.Wang@fda.hhs.gov>

Subject: STN 125696/0 Aimimmune-Information Request # 59 (REMS)

Dear Bill and Louise,

The following comments are based on the Agency's ongoing review of the proposed REMS for Palforzia, BLA 125696. Materials submitted on January 31, 2020 in response to Agency comments issued January 30, 2020 are the subject of this review.

REMS Document:

The Agency reviewed your document submitted on January 30, 2020 and no changes are required at this time.

REMS Appended Materials:

Patient Enrollment Form

- In the Patient Agreement section, remove "Initial Dose Escalation" to be consistent with the REMS Document. This information is explained in the bullet above that states the patient will receive monitoring at treatment initiation from the prescriber. See edit below.
 - During treatment (before ~~the Initial Dose Escalation~~ and the first dose of each Up-Dosing level):
 - Receive counseling from a healthcare provider on the need to be monitored for severe allergic reaction (anaphylaxis)

Education Program for Healthcare Settings

- **Slide 6** – In the section on Patients, remove "Initial Dose Escalation" to be consistent with the REMS Document. This information is explained in the bullet above that states the patient will receive monitoring at treatment initiation from the prescriber. See edit below.
 - During treatment (before ~~the Initial Dose Escalation~~ and the first dose of each Up-Dosing level):
 - Receive counseling from a healthcare provider on the need to be monitored for severe allergic reaction (anaphylaxis)

There are no changes required to the following materials at this time:

- Prescriber Enrollment Form
- Healthcare Setting Enrollment Form
- Pharmacy Enrollment Form
- Wholesaler-Distributor Enrollment Form
- REMS Program Overview for Pharmacies
- Website Screenshots

REMS Supporting Document:

In section 4.3, Palforzia Will Be Dispensed Only to Patients with Evidence of Safe Use Conditions, number 3: Remove “Initial Dose Escalation” from the first bullet as described above. See edit below.

3. By signing the *Patient Enrollment Form*, the patient and/or parent/guardian acknowledges that the patient will:

- During treatment (before ~~the Initial Dose Escalation and~~ the first dose of each Up-Dosing level):
 - Receive counseling from a healthcare provider on the need to be monitored for anaphylaxis during treatment.
- During treatment (during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes):
 - Be monitored for anaphylaxis at the healthcare setting.

Resubmission Instructions:

Your complete REMS proposal (REMS document, all appended materials and supporting document) should be submitted as separate documents in the same submission, to include both a Microsoft Word tracked changes version, a Microsoft Word clean version, as well as a .pdf version of the REMS document and each of the appended materials. The only exception is the REMS Website screenshots which may be submitted as a .pdf version only.

Kind Regards
Taruna

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