

From: Cagungun, Nannette
Sent: Tuesday, June 28, 2016 10:48 AM
To: 'jcastillo@Portola.com'
Subject: Information Request

Our Reference: BL 125586/0

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for Coagulation Factor Xa (Recombinant), Inactivated, and have the following request regarding the release specification for Polysorbate 80:

1. On April 20, 2016, you indicated that you are developing a method for the detection and quantitation of Polysorbate 80 in andexanet alfa. In addition to our request for sucrose and mannitol, submitted on 22 June 2016, please include acceptance limits for Polysorbate 80 in the drug product specification by August 1, 2016, and commit to completing the method validation by October 31, 2016 and re-evaluate the acceptance limits after you have obtained data from 20 batches of drug product or one year post licensure, whichever comes first.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by July 8, 2016 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is August 17, 2016.

If you have any questions, please contact LT Maruna at (240) 402-8454.

Sincerely,

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