

From: Maruna, Thomas
Sent: Monday, January 25, 2016 3:35 PM
To: 'Janice Castillo'
Subject: Pre-Filing Information Request (2) - BLA 125586.0 - Please Respond by January 29. 2016

Importance: High

(b) (6)

Attention: Ms. Janice Castillo
January 25, 2016
Sent by email

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for the following:

STN	Name of Biological Products
125586/0	Coagulation Factor Xa (Recombinant), Inactivated

We determined that the following information is necessary to continue our review:

1. The Comparability Protocol provided specifically, NC-15-0664-P0001, “ Andexanet Alfa Drug Substance Comparability of (b) (4) to (b) (4) is missing significant information and details in regards to the changes in the facility and equipment involved in the manufacturing change to use the (b) (4) . The comparability protocol should include the following specifics:
 - A detailed description of the changes in the facility (renovations, HVAC, etc.) and the equipment used (b) (4) etc.).
 - A listing and description of specific tests that will be performed for the qualification (OQ/PQ) of the “new” area and the “new” equipment used for the manufacturing change, in addition, a listing of the acceptance criteria that will be used for the qualification testing to be performed.
2. Please indicate the specific labeling activities that are performed at Packaging Coordinators facility. Does this labeling involve primary labeling of the final container or labeling of the secondary packaging?
3. Please provide more details for the activities (Drug Substance QA and Final Batch Disposition) performed at Portola Pharmaceuticals (San Francisco, CA). Do these activities involve handling and storage of drug substance and/or drug pro(b) (4)

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 responses as an amendment to this file by January 29, 2016 referencing the date of this request.

The action due date for these files is August 17, 2016.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP)^{CM}

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