
Valencia, Iliana

From: Valencia, Iliana
Sent: Thursday, June 23, 2016 6:17 PM
To: 'jcastillo@portola.com'
Subject: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Information Request
Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
June 23, 2016 Sent
by email

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for 125586/0 Coagulation Factor Xa (Recombinant), Inactivated.

We have reviewed the certificates of analysis provided with your samples for testing on 29 February, 2016, as part of your submission under STN 125586/0.8 and have the following request:

Direct and Indirect Potency Assays

Please provide your results for the Direct (b) (4) , using TME-0580, and Indirect (b) (4) , using TME-0583, for the following lots of drug product submitted to CBER for testing:

- M7173A
- M7177A

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 **July 6, 2016**. If you are unable to do so, please let me know so that we can discuss a possible alternate time for submission.

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

Sincerely,

Iliana Valencia, MS, MCPM
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IO 240-402-
8444 iliana.valencia@fda.hhs.gov

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