Valencia, Iliana

From: Valencia, Iliana
Sent: Friday, June 24, 2016 4:50 PM
To: jcastillo@portola.com
Subject: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to Information Request of May 3, 2016

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
June 24, 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.

On May 3, 2016, we submitted the following request:

Please provide 10 mL of formulated Coagulation Factor Xa (Recombinant), Inactivated drug product (STN: 125586) obtained from the manufacturing line before the lyophilization step for evaluation in our laboratory in support of your BLA submission. You may send us non-cGMP drug product (but not drug substance) in lieu of the drug product formulated under cGMP, as long as the product is scientifically representative of the drug product final formulation. We request that you send us the sample within 2 weeks of receiving this request. If you are unable to do so, please let us know the date when you will be able to send us the requested materials.

We had a teleconference with you on May 5, 2016 at your request in which we explained why we needed the material. We also told you that we do not need 10 mL sample, about 2 mL would be sufficient. You told us that you will let us know when you will send us the material. However, to this date we have not received the material or any time-frame from you when we will receive the material from you.

Please send the requested material to the following address:

Hsiaoling Wang
Division of Biological Standard and Quality Control
CBER / FDA
Bldg. 75, Room G662
10903 New Hampshire Avenue
Silver Spring, MD 20993

We have asked for this information to be submitted by May 10, 2016. You did not comply with this request nor did you propose a timeframe for submission. As we have indicated receiving the material in sufficient advance will allow us reasonable time to analyze it to complete review of your BLA submission within the stipulated timeline. Please submit this information by no later than Monday, June 27th. Any additional delays on your behalf might affect the review in the stipulated timeline.

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

The action due date for this file 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