
Valencia, Iliana

From: Valencia, Iliana
Sent: Friday, July 01, 2016 3:26 PM
To: jcastillo@portola.com
Subject: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to the June 22 meeting.

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
July 1, 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.

As a follow up to the June 22, 2016 face-to-face meeting, Dr. Verdun asked that Portola submits the revised protocol for the ongoing P3b/4 study within two weeks of the meeting. During the face-to-face meeting Dr. Marks provided suggestions. This email serves as a reminder to submit the revised protocol including Dr. Marks suggestions. Please submit the protocol by no later than July 6, 2016.

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

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