

Valencia, Iliana

From: Valencia, Iliana
Sent: Friday, June 24, 2016 5:13 PM
To: jcastillo@portola.com
Subject: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Information Request
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. We have the following request:

CMC Information Request on (b) (4) experiments:

With reference to your June 17, 2016 response to the May 4, 2016 request for additional information on (b) (4) experiments, we acknowledge your commitment to provide the **full Study Report by July 1, 2016**. In this report, please provide the following information:

- a) The (b) (4) for each (b) (4) experiment. Please report the data in the form of a table by expanding Table 1.11.1-1 *Tabulation of (b) (4) Results for the Binding between Andexanet alfa and Four Direct Inhibitors using (b) (4)* provided in your June 17, 2016 amendment to BLA 125586/0.
- b) The representative (b) (4) profiles for the binding of andexanet alfa from (b) (4) with apixaban, (b) (4), edoxaban, and rivaroxaban. Please report the data in the form of raw data and binding isotherms as described in IND 15089, Section 3.2.S.3.1.11, Figure 3.2.S.3.110.

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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