

From: Maruna, Thomas
Sent: Monday, March 07, 2016 1:06 PM
To: 'Janice Castillo'
Cc: Campbell, Karen M
Subject: Request for Standards, Reagents and Samples (Revised) for BLA 125586.0 - Please Submit by March 21. 2016

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
March 7, 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

CBER requests that you provide the following standards, reagents and samples for testing in-support of your BLA submission (STN: 125586) as soon as possible, preferable 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.

1. Samples – In addition to what you have sent for the potency assays, please provide 2 vials each from ^{(b) (4)} lots of your drug product manufactured under full cGMP for in-support testing.

2. Reagents

(b) (4) [Redacted]
(b) (4) [Redacted]
(b) (4) [Redacted]
(b) (4) [Redacted]

3. please provide,
 - a. The quality control test results, if not already included in the BLA for each drug product lot being provided
 - b. The assigned values for the reference standards requested if different from document QST-0025.

4. Is it possible to divide the reconstituted sample and store them in small aliquots either at low temperature (b) (4), and for how long and in what type of container (glass, polycarbonate, etc.)? What will be the impact of such storage on (a) purity assays and (b) potency assays? Please provide data in support of the information, to the extent available.

Ship reagents, standards, controls and drug product samples to the address listed below:

Mark Levi
Center for Biological Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-662
Silver Spring, MD 20993-0002

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 these files is August 17, 2016.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
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