

From: Maruna, Thomas
Sent: Monday, January 25, 2016 12:43 PM
To: 'Janice Castillo'
Cc: Ovanesov, Mikhail V.
Subject: Pre-Filing Information Request - BLA 125586.0 - Please Respond by January 29. 2016

Importance: High

Attention: Ms. Janice Castillo
January 25, 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

We determined that the following information is necessary to continue our review:

1. Please provide an estimated completion date for the ongoing qualification of the sterility test for the final drug product (FDP), and for the submission of the final report to the BLA.
2. Please provide the full reports of the method bridging studies including, but not be limited to, Report AD-2015-001-007, Version 3 (referenced in section 3.2.S.4.5).
3. Please clarify which of the FDP release test methods were validated using only the Bulk Drug Substance (BDS).
4. Please provide information on the source of the *sterile Water for Injection* you used in the validation of the test methods for the establishment of the FDP specifications and the analysis of FDP batches.
5. Please submit a Pharmacovigilance (risk management) Plan.

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 January 29, 2016 referencing the date of this request.

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)^{CM}

Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.