

STN 1255060 Information Request.txt

From: Rana, Pratibha
Sent: Friday, August 28, 2015 3:39 PM
To: MaryAnn Lamb (MaryAnn.Lamb@bpl-us.com)
Subject: STN 125506/0 Information Request

Our Reference: STN 125506
Bio Products Laboratory

Dear Dr. Lamb:

We are reviewing your biologics license application (BLA) for Coagulation Factor X (Human) and have the following information request.

Validation of Procedure for Determination of (b) (4)

1. (b) (4)

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

Please submit your responses as an amendment to this file by September 11, 2015, referencing the date of this request.

The action due date for this file is October 27, 2015.

Please call me or contact me at pratibha.rana@fda.hhs.gov
Pratibha

Pratibha Rana, M.S.
Regulatory Project Manager
email: pratibha.rana@fda.hhs.gov

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