

STN 1255060 Information Request .txt

From: Rana, Prati bha
Sent: Monday, October 19, 2015 5:36 PM
To: 'MaryAnn Lamb'
Cc: Val enci a, I l i a n a
Subject: STN 125506/0 Information Request
Attachments: fi nal -draft-physi ci an l abel i ng-text-cl ean (2). docx

Our Reference: STN 125506
Bi o Products Laboratory

Dear Dr. Lamb:

We are reviewing your biologics license application (BLA) for Coagulation Factor X (Human) and have the following information request. Please see the attached PI as Word Document.

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

Please send me email confirmation (statement) stating that you agree to the proposed changes by no later than 9 am EST. Please CC. I l i a n a Val enci a in all communication.

Please submit your responses as an amendment to this file asap no later than October 20, 2015 referencing the date of this request. The action due date for this file is October 27, 2015.

I will also speak to you on the phone.

Please call me or contact me at prati bha.rana@fda.hhs.gov

Prati bha

Prati bha Rana, M. S.
Regulatory Project Manager

FDA/CBER/OBRR
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