

From: Maruna, Thomas
Sent: Friday, January 27, 2017 7:03 PM
To: Ammons, Stanley
Cc: Peng, Ze; Tobin, Grainne A.
Subject: 27-Jan-2017 Information Request - BLA 125612.0 - Response Due NO-LATER-THAN 03-Feb-2017

Importance: High

STN: BL 125612/0

BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
January 27, 2017
Sent by email

Dear Mr. Ammons:

We are reviewing your biologics license application (BLA) dated June 9, 2016, for Fibrinogen Concentrate (Human), and have determined that the following information is necessary to take complete action. Please promptly submit your written response to the following items so that we may continue evaluating your BLA:

1. We have reviewed your responses to Information Requests in Amendment 21, received December 7, 2016, and Amendment 27, received January 5, 2017, and have the following additional request for information concerning the determination of fibrinogen by (b) (4) method:

We are confused by your response in Amendment 27, that the most recent version of your SOP, 130SOP111, is version 6, submitted with your initial submission. In Amendment 21, you stated that the Fibrinogen by (b) (4) assay is currently being revalidated because you have introduced a (b) (4). Furthermore, as part of the revalidation, you have evaluated (b) (4) provided data in your response to our IRs in Amendment 21, using (b) (4) are mentioned in version 6 of your SOP, suggesting that you are now using a new or significantly revised procedure. We are therefore repeating our request for the latest version of your SOP, as requested in our previous IR, dated December 21, 2016, to complete the review and carry out in-support testing for your BLA.

Please submit your response in a timely manner, as noted below, so we may continue the review of your application. If we determine that your response to this information request constitutes a major amendment, we will notify you in writing. If we receive your

major amendment during the last three months of the review period, we will extend the review period an additional three months.

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 **NO-LATER-THAN** February 3, 2017, referencing the date of this request.

The action due date for these files is June 9, 2016.

If you have any questions, you may contact me directly.

Very Respectfully,

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