From: Maruna, Thomas
Sent: Thursday, December 15, 2016 3:59 PM
To: Ammons, Stanley
Cc: Peng, Ze
Subject: 15-Dec-2016 Information Request - BLA 125612.0 - Response Due 06-Jan-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
December 15, 2016
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. Please include the testing of (b) (4), a process-related impurity, and its acceptance criterion in the release specifications of the final drug product (FDP) of Fibrinogen (Human). Please submit the standard operating procedure, and the method validation report for this analytical method to the BLA.

2. Please include (b) (4) in the release specifications of the FDP of Fibrinogen (Human) to control the (b) (4) and purity of the FDP. Please submit the standard operating procedures, and the method validation reports for these analytical methods to the BLA.

3. In your manufacturing process, the clearance of non-enveloped viruses primarily relies on the nanofiltration step in the manufacturing process. Therefore, a physical segregation (e.g., wall) between the pre- and post-nanofiltration steps in your manufacturing process is essential in avoiding cross contamination of the pre- and post-filtered materials and ensuring viral safety of the product. Please consider physical segregation of the pre- and post-viral cleared materials for the nanofiltration step in your manufacturing process

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 by January 6, 2017, referencing the date of this request.

The action due date for these files is June 21, 2016.

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

Very Respectfully,

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