From: Maruna, Thomas
Sent: Wednesday, March 08, 2017 9:18 AM
To: Ammons, Stanley
Cc: Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com); Patel, Sapana
Subject: 08-Mar-2017 Information Request - BLA 125612.0 - Response due 10-Mar-2017

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
March 8, 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. In your response to the Agency's December 21, 2016, response received by the Agency on January 5, 2017, you have reference Exhibit 13C which contains your (b) (4) qualification report; however, we were unable to locate this in your response. Please provide Exhibit 13C for.

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.

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 March 10, 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
Lieutenant Commander, U.S. Public Health Service
Senior Regulatory Management Officer

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thomas.maruna@fda.hhs.gov
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