From: Maruna, Thomas
Sent: Wednesday, May 03, 2017 10:03 AM
To: 'Ammons, Stanley'; Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com)
Cc: Barash, Faith
Subject: 03-May-2017 Information Request - BLA 125612.0 - Response due 10-May-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
May 3, 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. Concerning the draft protocol for a post-marketing study on the safety and efficacy of Fibryna, please submit details on the study timeline and milestone dates, including target date of final protocol and final report.

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 May 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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