

**From:** Maruna, Thomas  
**Sent:** Tuesday, May 16, 2017 10:18 AM  
**To:** Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com); 'Ammons, Stanley'  
**Cc:** Barash, Faith  
**Subject:** 16-May-2017 Information Request - BLA 125612.0 - Response due 23-May-2017

**Importance:** High

STN: BL 125612/0

**BLA INFORMATION REQUEST**

Octapharma Pharmazeutika Produktionsges.m.b.H.  
Attention: Mr. Stanley Ammons  
May 16, 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:

Thank you for providing the draft protocol for a post-marketing study on the safety and efficacy of Fibryna and for submitting the details on the study milestone dates.

1. Please modify the protocol to reflect that a **minimum of 10** patients with major bleeding will be evaluated.
2. Please explain the use of the "Wells Score". Specifically, is this algorithm a tool to determine who requires higher level diagnostic testing?
3. Please modify the protocol such that all suspected cases of thrombosis will be fully evaluated using all available modalities and all suspected cases of thrombosis (DVT, PE or other) require clinical confirmation.

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 23, 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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