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|---|---|
| **From:** | Maruna, Thomas |
| **Sent:** | Tuesday, May 30, 2017 9:39 AM |
| **To:** | 'Ammons, Stanley'; Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com) |
| **Cc:** | Barash, Faith; Peng, Ze |
| **Subject:** | 30-May-2017 Information Request - BLA 125612.0 - Response due 02-June-2017 |
| **Importance:** | High |

STN: BL 125612/0
**BLA INFORMATION REQUEST**

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
May 30, 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. The Octapharma FIBRYNA postmarketing study outline, Version 02, dated May 19, 2017, Subject/Patient Selection Inclusion Criteria includes "patients of any age" and those receiving Fibryna for "surgical prophylaxis."

   Please modify the Subject/Patient Selection Inclusion Criteria as follows: patients ≥ 12 years of age; receiving Fibryna for the treatment of acute bleeding episodes.

Please submit your response in a timely manner, as noted below, so we may continue the review of your application.

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 June 2, 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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