To: stanley.ammons@octapharma.com
Cc: Maruna, Thomas
Subject: Information Request for BLA 125612/0

Contacts: Stanley Ammons - Octapharma

STN: BL 125612/0
BLA INFORMATION REQUEST
Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
April 21, 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:

Our review of the original BLA 125612/0 for human fibrinogen concentrate (proposed trade name, Fibryna) is ongoing. Should the product be approved, pursuant to Section 505(o) of the FDCA (amended by FDAAA, Title IX, Section 901), Octapharma may be required to conduct a postmarketing study (PMR) to further characterize the risks of thrombosis and anaphylaxis following Fibryna use for major bleeding events in patients with congenital afibrinogenemia. Please propose a postmarketing study to further assess these safety concerns and include the following information in the study proposal for safety evaluation of Fibryna for major bleeding events: study design, minimum number of major bleeding events to be captured, sample size, statistical analysis plan, information to be collected at baseline, frequency and methods for follow-up data collection, information to be collected in follow-up, study timeline and milestone dates.

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 April 27, 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 Tom Maruna as he is cc in this message.

Thank you,

Edward Thompson
Regulatory Project Manager

Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-8443
edward.thompson@fda.hhs.gov