Our Reference: BLA under STN 125612/0

Date: December 8, 2016

Octapharma Pharmazeutika Produktionsges.m.b.H.

ATTENTION: Mr. Stanley Ammons
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

Attached is a copy of the agenda for your December 12, 2016 Mid-Cycle Communication Teleconference with CBER.

Please include a reference to Submission BLA # 125612 in your future submissions related to the subject product.

If you have any questions regarding the above, please contact Thomas Maruna, at (240) 402 8454 or thomas.maruna@fda.hhs.gov

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application type and number: BLA under STN 125612/0

Product name: Fibrinogen (Human)

Proposed Indication: For the treatment of acute bleeding episodes (b) (4) in adult and pediatric patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia

Applicant: Octapharma Pharmazeutika Produktionsges.m.b.H.

Meeting date & time: December 12, 2016, 10:00 am to 11:00 am EST

Committee Chair: Ze Peng

RPM: Lorraine Wood

Agenda:

Discussion Summary:

1. **Any significant issues/major deficiencies, categorized by discipline, identified by the review committee to date.**

   No significant issues or major deficiencies have been identified by the review committee to date.

2. **Information regarding major safety concerns.**

   The review of the clinical data to date did not raise major safety concerns.

3. **Preliminary review committee thinking regarding risk management.**

   The current thinking of the review committee is that a *Risk Evaluation and Mitigation Strategy* (REMS) is not required. However, routine pharmacovigilance is recommended.

4. **Any information requests sent and responses not received**

   FDA sent two *Information Requests* (IRs) on 27 September 2016 and 18 November 2016, for which FDA has not yet received the responses from Octapharma.

Responses to the IRs dated 12 October, 26 October, 7 November, 10 November, and 22 November 2016 were received, and are under review.

5. Any new information requests to be communicated

FDA will send Octapharma IRs on the release specifications of the drug product, the physical segregation of the unit operations before and after the nanofiltration step, and *Design Control Inputs* related to the Octajet and filter devices, by the end of December 2016. Please note that the review is ongoing and additional information may be requested as the need arises.

6. Proposed date for the Late-Cycle meeting

i. The *Late-Cycle Meeting* (LCM) is tentatively scheduled for Wednesday, 22 February 2017, and the format of the meeting will be determined at a later date.

ii. We intend to send the LCM briefing materials to you ~2 days before the LCM.

iii. If these timelines change, we will inform you during the review.

7. Updates regarding plans for the Advisory Committee meeting

The current thinking of the review committee is that this BLA will not be presented at the meeting with the *Blood Products Advisory Committee.*

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

The action due date for this BLA is Friday, 9 June 2017.