Our Reference: STN BL 125612/0

Octapharma Pharmazeutika Produktionsges.m.b.H.
ATTENTION: Mr. Stanley Ammons
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

Attached is a summary of your December 12, 2016, Mid-Cycle Communication Teleconference with CBER. This memorandum constitutes the official record of the teleconference. If your understanding of the teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to STN BL 125612/0 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 Summary

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 a.m. to 11 a.m., EST

Committee Chair: Ze Peng

RPM: Lorraine Wood

Purpose: To provide an update on the review of the BLA

Attendees:

FDA Attendees:
Thomas Maruna, Regulatory Project Manager, OTAT/DRPM
Ze Peng, Chairperson, OTAT/DPPT/HB
Lorraine Wood, Regulatory Project Manager, OBRR/IO

Octapharma Pharmazeutika Attendees:
Stanley Ammons, Senior Director, Compliance & Government Policy
Martina Bayer, Process/Technology Expert
Anna Edlinger, Int. Drug Regulatory Affairs Manager
Thomas Ernegger, Head of cQC Stability study
Werner Giefing, Head of Quality Assurance
Oliver Hegener, VP Head of IBU Critical Care
Andrea Jungmann, Deputy Head of cQC Method Validation
Sigurd Knaub, Board Member
Harald Mayer, Head of Operations Support
Nina Prieß, Int. Drug Regulatory Affairs Manager
Barbara Rangetiner, Director, Int. Drug Regulatory Affairs
Jürgen Römisch, Senior VP, R&D Plasma
Petra Schulz, Senior Scientist
Cristina Solomon, Senior Director, Clinical R&D
Eva Sychrovsky, Head of Validation Operations Support
Josef Trenkwalder, Head of Microbiology

Discussion Summary:

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

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

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

   Octapharma stated that the FDA IR dated September 27, 2016, was not forwarded internally at Octapharma until December 9, 2016. Octapharma will provide a response to the IR as soon as possible.

5. 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. FDA noted that the review is ongoing and additional information may be requested as the need arises.

6. The *Late-Cycle Meeting* (LCM) is tentatively scheduled for Wednesday, February 22, 2017, and the format of the meeting will be determined at a later date. FDA intends to send the LCM briefing materials to Octapharma 2 days before the LCM. If these timelines change, FDA will inform Octapharma during the review.

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