DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125612/0

BLA FILING NOTIFICATION

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

Dear Mr. Ammons:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated June 09, 2016, for Fibrinogen Concentrate (Human) to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is June 09, 2017. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which include the timeframes for FDA internal milestone meetings. We plan to hold our internal mid-cycle review meeting on November 23, 2016. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

We will contact you regarding your proposed labeling no later than May 10, 2017. If post marketing study commitments (506B) are required, we will contact you no later than May 10, 2017.

We are not currently planning to hold an advisory committee meeting to discuss this application.

While conducting the filing review, we concluded that your product, which will be co-packaged with a transfer device and filter, is a combination product and needs to be in compliance with the following regulations: Management Responsibility (820.20), Design Controls (820.30), Purchasing Controls (820.50), and Corrective and Preventive Action (820.100) as specified in 21 CFR 4.4. Please submit information to demonstrate compliance with the above mentioned regulations which should also include information on the design of the current device, design

history, design verification studies, and all Human Factors studies as an amendment to this BLA by September 2, 2016.

We are providing the above comments to give you preliminary notice of potential review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our complete review. Issues may be added, deleted, expanded upon, or modified as we review the application. If you respond to these issues during this review cycle, we may not consider your response before we take an action on your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Lorraine Wood, at (240) 402-8439 and lorraine.wood@fda.hhs.gov.

Sincerely yours,

Iliana Valencia, MS, MCPM,
Chief, Regulatory Project Management Staff
Office of Blood Research and Review
Center for Biologics Evaluation and Research