From: Maruna, Thomas
Sent: Wednesday, December 21, 2016 1:31 PM
To: Ammons, Stanley
Subject: 21-Dec-2016 Information Request - BLA 125612.0 - Response Due NO-LATER-THAN 06-Jan-2017 and 09-Mar-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
December 21, 2016
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. You state that the Octajet is a (b) (4) . Please provide the following information within your BLA submission:

   Design Control Inputs to include:

   • Design Requirement Specifications
   • Device Verification/Validation Data in the BLA or cross referenced to a master file
   • Traceability Documentation
   • Biocompatibility testing based upon the biological evaluation of medical devices.
   • Sterility testing
   • Performance requirements of the device constituents including but not limited to leakage testing, flow rate, visual inspection, attachment force, testing in accordance to ISO 594
   • Lot Release Specifications and Testing
   • Labeling

   Please provide full test reports for all tests performed.

2. We are also unable to locate the Letter of Reference for the proposed filter. Please provide the Letter of Reference or provide the Design Control Inputs as requested for the transfer device for the filter.

3. We have reviewed your Responses to Information Requests, in Amendment 20, dated December 7, 2016, and Amendment 24, dated December 14, 2016. Please submit the following:

Determination of Fibrinogen by (b) (4)

a. Please provide the most recent version of your master SOP, 130SOP111, Determination of Fibrinogen by (b) (4) .

b. You have indicated that you will submit an updated validation report, 000VAL111 FC 000VAL111 FC 34/x /02, by the end of April 2017. However as the First Action Due Date is June 9, 2017, this timeline will not provide sufficient time to complete our review of the new information. Please provide your updated validation report **NO-LATER-THAN March 9, 2017**.

Determination of (b) (4) **in Fibrinogen Final Containers According to** (b) (4)

c. You have indicated that you will provide additional data for linearity, range, robustness and accuracy by 15 April 2017. Please provide the data **NO-LATER-THAN March 9, 2017**, to allow adequate time to complete our review before the Action Due Date of June 9, 2017.

Determination of (b) (4) **Method**

d. You have indicated that additional data for accuracy will be provided by 15 April 2017. Please provide the data **NO-LATER-THAN March 9, 2017**, to allow adequate time to complete our review before the Action Due Date of June 9, 2017.

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. If we receive your major amendment during the last three months of the review period, we will extend the review period an additional three months.

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** the dates indicated above, 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
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Tissue and Advanced Therapies
10903 New Hampshire Ave.
Silver Spring, MD 20993
thomas.maruna@fda.hhs.gov
O: (240) 402-8454
www.usphs.gov