From: Maruna, Thomas
Sent: Monday, January 09, 2017 4:01 PM
To: 'Ammons, Stanley'
Cc: Peng, Ze
Subject: 09-Jan-2017 (Revised) Information Request - BLA 125612.0 - Response Due NO-LATER-THAN 11-Jan-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
January 9, 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:

1. Please clarify whether U.S. Source Plasma (21 CFR 640.60) is the only plasma used in the manufacture of Fibrinogen (Human) for the proposed U.S. market. If recovered plasma is also used, please provide the short supply agreement(s) between Octapharma and the supplier(s) of the recovered plasma.

2. In reference to your January 4, 2017, amendment (received January 5, 2017) in response to our Information Request dated December 21, 2016, please address the following:

    a. In Question 1 of your response to our Information Request, we requested you provide:

        - Design Requirement Specifications
        - Device Verification/Validation Data
        - Traceability Documentation (ie. dFMEA)
        - Lot Release Specifications and Testing

        You have provided information in this response which is considered for general use of the device not specific to Fibrinogen vial. Please provide the information above as it applies to your combination product. Please provide the information in a table format for each of the requested information.

Please note the performance requirements should also be tested with your proposed drug vial. If the testing provided does not apply to your drug please provide testing with your drug or provide a rationale to why the testing provided is appropriate. Please note the full test reports have not fully been reviewed.

3. We request the following regarding the Lot Release Protocol Template submitted in 125428/0 on 09-June-2016:

    a. On pages 2, and 3 of 4, Remove Sterile from the sterility test specification, the specification should be No Growth.

    b. On page 2 of 4, General Safety, please change the specification to complies with 21CFR 610.11

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** January 11, 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 me directly.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
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