From: Maruna, Thomas
Sent: Tuesday, May 09, 2017 9:59 AM
To: 'Ammons, Stanley'; Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com)
Cc: Peng, Ze; Patel, Sapana
Subject: 09-May-2017 Information Request - BLA 125612.0 - Response due 10-May-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
May 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:

Please find below the deficiencies to the tests performed on the Octajet. There are a few tests which are unclear as to how they were performed on the device or which part of the device they are performed on.

1. In section 5.3 you stated you have conducted air and liquid leakage testing in accordance to ISO 594-2 which included a luer lock fitting. You have stated that you conducted this testing of the junction and spikes. It is unclear of the protocol followed for testing of the spikes. Please clearly describe how testing was performed for air and liquid leakage in accordance to ISO 594 for the spikes. You also stated testing was conducted on the junction, however you have not clearly identified the junction on which testing was conducted. Please clarify how testing was performed on the spikes and junction using ISO 594 testing for luer connections.

2. You have stated in section 5.4 that you conducted separation pull force to ISO 8536. ISO 8536 is the standard for infusion sets for gravity use and it is unclear how it is applicable to your device. It is unclear which section of ISO 8536 refers to separation pull force of the vial from the transfer spike. Please clarify which section of the standard to which you performed your testing.

3. In Section 5.5 you have performed testing to ISO 594, however it is unclear which component of the Octajet the tests were performed on. Please clearly identify which component all tests were performed on.

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.

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 May 10, 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
Lieutenant Commander, U.S. Public Health Service
Senior Regulatory Management Officer

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