

From: Maruna, Thomas
Sent: Tuesday, April 18, 2017 11:05 AM
To: Ammons, Stanley
Cc: Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com); Patel, Sapana; Peng, Ze
Subject: 18-Apr-2017 Information Request - BLA 125612.0 - Response due 19-Apr-2017

Importance: High

STN: BL 125612/0

BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
April 18, 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:

You stated in your response to the Agency on February 24, 2017, that additional tests were to be performed on the Octajet, which included:

1. *Testing of attachment force and or penetration force*
2. *Leakage testing (liquid and air) for both, Product and Water spike as well as junction according to ISO 7886 and ISO 594*
3. *ISO 594 compliance verification testing of the female luer lock port as an integral part of the product spike including:*
 - a. *Dimensional control acc. ISO 594-1 § 5.1 (calibrated test jig)*
 - b. *Leakage assessment acc. ISO 594-2 – § 5.2 & §5.3 (water & air)*
 - c. *Disconnection force acc. ISO 594-2 § 5.4*
 - d. *Torque verification acc. ISO 594-2 § 5.5*
 - e. *Screw connection verification acc. ISO 594-2 § 5.6*
 - f. *Overriding force verification acc. ISO 594-2 § 5.7*
 - g. *Stress cracking test acc ISO 594-2 § 5.8*

(b) (4)

We are unable to locate this information in your April 7, 2017, response, test, Octajet SSR 1 year report.

1. Please provide the location of this information in your report.
2. Please include as previously stated the raw data for the test conducted.
3. Please also provide a table which includes the acceptance criteria, number of samples tested, results and conclusion.

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 April 19, 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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