From:	Maruna, Thomas
Sent:	Thursday, March 23, 2017 3:08 PM
To:	'Ammons, Stanley'
Cc:	Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com); Patel, Sapana; Peng, Ze
Subject:	RE: 22-Mar-2017 Information Request - BLA 125612.0 - Response due 28-Mar-2017

Mr. Ammons,

This correspondence pertains to item number 2 in the March 22, 2017, IR:

> 2. *In your response to the February 6, 2017 IR you stated that to support functionality of the combination product testing will be submitted as part of a post approval commitment. You have stated functionality testing of the combination product will be performed in accordance to ISO 130SOP006, however we are unable to locate essential performance testing of the combination product after shipping in the transport validation protocol. Please provide a table format the post approval combination product testing you intend to perform.*

Please note that in Lieu of a post market commitment for the essential performance testing of the device constituent of the combination product, stability data to support the essential performance requirements of the device constituent would be considered for review.

Please indicate if you have any questions.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
Lieutenant Commander, U.S. Public Health Service
Senior Regulatory Management Officer

Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
O: (240) 402-8454
thomas.maruna@fda.hhs.gov

From: Maruna, Thomas
Sent: Wednesday, March 22, 2017 3:14 PM
To: Ammons, Stanley
Cc: Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com); Patel, Sapana; Peng, Ze
Subject: 22-Mar-2017 Information Request - BLA 125612.0 - Response due 28-Mar-2017

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
March 22, 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. In your response to the February 6, 2017 IR you provided a draft Octajet test protocol for functional testing. Please note when submitting your full test report please state if the testing has been conducted with the drug vial. If testing is completed with a surrogate vial, please provide a side-by-side comparison of both drug vials. We also expect that the full test report will be submitted for review. You have also stated that you will be conducting tests in accordance to ISO 7886. ISO 7886 relates to sterile hypodermic syringes for single use and we are unclear how this standard applies to your device. Please provide a statement to how this standard will relate to your device when submitting the test report for review.

2. In your response to the February 6, 2017 IR you stated that to support functionality of the combination product testing will be submitted as part of a post approval commitment. You have stated functionality testing of the combination product will be performed in accordance to ISO 130SOP006, however we are unable to locate essential performance testing of the combination product after shipping in the

transport validation protocol. Please provide a table format the post approval combination product testing you intend to perform.

3. In your response to the March 8, 2017 you provided Exhibit 13 C. Within Exhibit 13C, you have provided seal strength testing for the subject device. However, this information is not sufficient. We request that you please address the following concerns:

    a. It is not clear whether you have performed seal strength testing on samples of the subject device (b) (4) . Please clearly state whether seal strength was evaluated for (b) (4) methods. Please be advised that package integrity testing should be performed on the subject device (b) (4) according to the validated sterilization methods described in your submission.

    b. It appears that seal strength is the only barrier testing that was provided for your subject device. Seal strength testing alone is insufficient to demonstrate that the proposed packaging maintains a sterile barrier throughout the claimed shelf life. Please provide additional testing such as ASTM F1929, Standard Test Method for Detecting Seal Leaks in Porous Package Materials by Dye Penetration, and ASTM F2096, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) to demonstrate that the packaging presents an impermeable barrier. Please refer to ISO 11607-1:2006/(R)2010, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging materials for more information related to appropriate package integrity testing.

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 March 28, 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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