From:	Maruna, Thomas
Sent:	Thursday, April 06, 2017 4:05 PM
To:	Ammons, Stanley
Cc:	Tobin, Grainne A.; Peng, Ze; Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com)
Subject:	06-Apr-2017 Information Request - BLA 125612.0 - Response due 13-Apr-2017
Importance:	High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
April 6, 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 provide the inspectional history, either by the FDA or other regulatory agencies, for the following contract manufacturing facilities:

   (b) (4)

2. Please list the countries where the reconstitution device, Octajet, is marketed.

3. We have reviewed your Responses to our Information Requests, in Amendment 36, received March 9, 2017:

   We do not agree that your reproducibility data alone constitute a co-validation study. A co-validation between the two laboratories should include linearity, accuracy, precision, and robustness data from both sites. To demonstrate comparable results between the two laboratories, please provide linearity and accuracy as well as robustness data from the Stockholm (OAB) laboratory. Alternatively, please perform comparability assessment testing between the two sites, measuring at least six passable lots of drug product and at least three lots each with potency lower and higher than the specification limits. Test samples with higher potency values may be obtained by spiking drug product with the International Standard, while test samples with lower potency values may be

obtained by partial denaturation of the product or dilution in the formulation buffer.

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 13, 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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