From: Maruna, Thomas
Sent: Friday, May 26, 2017 6:19 PM
To: 'Ammons, Stanley'; Mayerhofer, Juliane (juliane.mayerhofer@octapharma.com)
Cc: Peng, Ze
Subject: 26-May-2017 Labeling Edits - BLA 125612.0 - Response due 31-May-2017

Importance: High

STN: BL 125612/0
BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
May 26, 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 attached our edits to the proposed labeling, to include the package insert (PI), carton, and container labels. Our edits to the carton and container labels are noted below. Please promptly submit your written response to the following items so that we may continue evaluating your BLA:

1. With reference to labeling in general, please use "Fibrinogen (Human)" as the proper name of your product

2. With reference to the carton, in the blue area, please add the word "Range" after "1 g". Under the heading of "1 bottle contains:" please provide the range of human fibrinogen instead of "1 g"

3. With reference to the container label, in the blue area, please add the word "Range" after "1 g". On the tab, please confirm that the actual potency of fibrinogen will be printed on this label

Please submit your response in a timely manner, as noted below, so we may continue the review of your application.

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 31, 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

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