

**From:** Maruna, Thomas  
**Sent:** Monday, June 05, 2017 11:26 AM  
**To:** 'Ammons, Stanley'; Mayerhofer, Juliane  
(juliane.mayerhofer@octapharma.com); Rangetiner, Barbara  
**Cc:** Peng, Ze  
**Subject:** 05-Jun-2017 Labeling Edits - BLA 125612.0 - Response due 06-Jun-2017

In addition to the PI labeling request below, we have the following comments concerning the carton labels:

1. For the Carton label, please correct the amount per bottle of **Glycine** and **L-Arginine hydrochloride** from 50 mg to 500 mg. Please respond to this information request (IR) by June 6, 2017; preferably together with your responses to the other IR regarding labeling (below).

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](mailto:thomas.maruna@fda.hhs.gov)



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**From:** Maruna, Thomas  
**Sent:** Friday, June 02, 2017 6:46 PM  
**To:** Ammons, Stanley; Mayerhofer, Juliane ([juliane.mayerhofer@octapharma.com](mailto:juliane.mayerhofer@octapharma.com))

Cc: Peng, Ze

Subject: 02-Jun-2017 Labeling Edits - BLA 125612.0 - Response due 05-Jun-2017

Importance: High

STN: BL 125612/0

**BLA INFORMATION REQUEST**

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

June 2 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. Please promptly submit your written response to the following items so that we may continue evaluating your BLA:



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 Jun 5, 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  
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