

From: Maruna, Thomas
Sent: Wednesday, December 07, 2016 2:38 PM
To: Ammons, Stanley
Cc: Baum, Victor
Subject: 07-Dec-2016 Information Request - BLA 125612.0 - Response Due 12-Dec-2016

Importance: High

STN: BL 125612/0

BLA INFORMATION REQUEST

Octapharma Pharmazeutika Produktionsges.m.b.H.

Attention: Mr. Stanley Ammons

December 7, 2016

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. We are reviewing your initial Pediatric Study Plan (iPSP) for Fibryna. The timeline presented in section 11, Timeline of the Pediatric Development Plan, is inadequate and does not meet the recommendations as delineated in the FDA Guidance "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans. Guidance for Industry."

To avoid a finding of materially incomplete, please resubmit your iPSP at your earliest convenience revising the timeline as follows:

[Estimated] protocol submission date: ____ (month/year)

[Estimated] study initiation date: ____ (month/year)

Estimated study completion date: No later than ____ (month/year)

Estimated final report submission date: No later than ____ (month/year)

2. As you revise the iPSP for resubmission, please also use the correct proprietary name for your product, Fibryna; not Octafibrin.

To avoid a finding of materially incomplete and additional delay, please resubmit your iPSP by **December 12, 2016**, or earlier.

Please submit your response in a timely manner, as noted above, 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 **December 12, 2016**, referencing the date of this request.

The action due date for these files is **June 9, 2017**.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
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