From:	Wood, Lorraine
To:	Ammons, Stanley
Subject:	Information Request for BLA 125612: PK Parameters
Date:	Wednesday, October 26, 2016 2:32:00 PM
Attachments:	image001.png image002.jpg image003.jpg image004.jpg image005.jpg image006.jpg
Importance:	High

Dear Mr. Ammons,

We are reviewing your submission for BLA 125612 and we request the following information to continue our review:

A prospective, controlled, randomized, crossover study investigating the pharmacokinetic properties, surrogate efficacy and safety of Octafibrin compared to Haemocomplettan P/RiaSTAPTM in patients with congenital fibrinogen deficiency **(FORMA-01).**

1. Please recalculate the PK parameters of Octafibrin and Haemocomplettan® P/RiaSTAPTM above LOQ ((b) (4)). In a Tabulated form, please provide age, weight, individual concentration-time data, and estimated PK parameters.

2. Please provide individual and mean concentration-time plots of Octafibrin and Haemocomplettan (above LOQ).

3. Please explore the relationship between plasma concentration (IVR at one hour) and maximum clot strength (which is also at one hour). For this analysis please use the data from studies FORMA-01 and FORMA-02. In a tabulated form, please submit the data (IVR and MCT) for individual subject.

4. When will you be able to submit the complete study report FORMA-04 (this study is ongoing) and what happened to FORMA-03?

Thank you

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