From:	Wood, Lorraine
To:	Ammons, Stanley
Subject:	Information Request for BLA 125612: Pediatric Study Plan
Date:	Monday, November 07, 2016 3:10:00 PM
Attachments:	image001.png
Importance:	High

Dear Mr. Ammons,

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

We continue to review your initial Pediatric Study Plan (iPSP) for Fibryna (submitted as amendment 3 to BLA 125612 in response to a July 7, 2016 FDA request). Specifically, the FDA request referenced the draft Guidance "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans Guidance for Industry" (March, 2016). Upon review of your Pediatric Study Plan we note it does not follow the very specific requirements of that document. An inadequate submission may result in an iPSP that is judged materially incomplete. Please submit an appropriate iPSP.

To avoid unnecessary delay in the review of your iPSP please respond by November 16, 2016.

Thank you
Lorraine

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