

From: [Wood, Lorraine](#)
To: [Ammons, Stanley](#)
Subject: Information Request for BLA 125612: Pediatric Study Plan
Date: Thursday, July 07, 2016 4:29:00 PM
Importance: High

Dear Mr. Ammons,

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

In reviewing the BLA for Fibryna we are unable to locate an initial pediatric study plan (iPSP), which is required no later than 60 calendar days after the end of a phase 2 meeting. While limited pediatric information is supplied in Section 1.9.6 of the BLA, we can locate no requests for a deferral or waiver of pediatric assessments for any age group(s). If this information exists, please identify its location. If not, this needs to be provided as soon as possible. Please reference the draft Guidance "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans Guidance for Industry"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).

Please respond with the location of this information and/or a proposed timeline by July 13, 2016.

Thank you

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