

**From:** [Wood, Lorraine](#)  
**To:** [Ammons, Stanley](#)  
**Subject:** Information Request for BLA 125612/0: Response Requested By October 9, 2016  
**Date:** Monday, September 19, 2016 2:02:00 PM  
**Importance:** High

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Dear Mr. Ammons,

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

We have reviewed the following quality control assays for the drug product and their validation reports submitted under STN 125612/0, and have the following Information Requests. Please submit your response by October 9, 2016. If you are unable to do so, please provide us the timeline for submission of the requested information.

**Determination of Fibrinogen by (b) (4)**

(b) (4)

[Redacted content]

(b) (4)

Thank you

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