

**From:** [Wood, Lorraine](#)  
**To:** [Ammons, Stanley](#)  
**Subject:** New Information Request for BLA 125612: Response Requested By July 8, 2016  
**Date:** Tuesday, July 05, 2016 2:29:00 PM

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Dear Mr. Ammons,

We are reviewing your submission for BLA 125612/0 and we request the following information to continue our review:

Please identify where in the BLA a rationale for assuming the applicability of foreign data to the U.S. population/practice of medicine resides. If not present, please supply it at this time.

Please respond to this request by July 8, 2016.

Thank you

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