

**From:** Maruna, Thomas  
**Sent:** Monday, November 10, 2014 9:46 AM  
**To:** Allison Kennedy (akennedy@ebsi.com)  
**Cc:** Fisher, Robert; Wang, Yonggang  
**Subject:** Information Requested: BLA 125562/0 - Please Respond by November 17, 2014

Cangene Corporation [Emergent Biosolutions]  
Attention: Ms. Allison Kennedy  
November 10, 2014  
Sent by email

Dear Ms. Kennedy:

We are reviewing your July 25, 2014 biologics license application (BLA) indicated for the treatment of adult and pediatric patients with toxemia associated with inhalational anthrax for the following:

<b>STN</b>	<b>Name of Biological Products</b>
BL 125562	Anthrax Immune Globulin Intravenous (Human)

We determined that the following information is necessary to continue our review:

1. Please provide the SOP and validation report for your (b) (4). Please indicate if this (b) (4) method has been calibrated with one of the following WHO (b) (4), and the limit of assay sensitivity is below (b) (4). If so, please provide all the available data for AIGIV lots testing measured in units of the (b) (4). If not, please provide a timeline for when Cangene can supply this data.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your responses as an amendment to this file by November 17, 2014 referencing the date of this request.

If Cangene is unable to respond by November 17<sup>th</sup>, please propose an alternative date to respond.

The action due date for these files is March 25, 2014.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP)<sup>CM</sup>

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