

**From:** Maruna, Thomas  
**Sent:** Tuesday, March 17, 2015 7:33 PM  
**To:** Allison Kennedy (akennedy@ebsi.com)  
**Cc:** Fisher, Robert  
**Subject:** BLA 125562.0 - Final PI for Review

**Importance:** High

Cangene Corporation [Emergent Biosolutions]  
Attention: Ms. Allison Kennedy  
March 17, 2015  
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 125562/0	Anthrax Immune Globulin Intravenous (Human)

We have reviewed your revised PI, and are providing our final version for your review (attached).



Should you have any concerns or edits, please contact Dr. Robert Fisher directly and copy me.

Please submit your responses as an amendment to this file by March 19, 2015.

If Cangene is unable to respond by the requested date, 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>  
Lieutenant, U.S. Public Health Service  
Senior Regulatory Management Officer

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