

## **Tilghman, Tracy**

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**From:** Tilghman, Tracy  
**Sent:** Monday, December 15, 2014 4:03 PM  
**To:** Allison Kennedy (akennedy@ebsi.com)  
**Cc:** Fisher, Robert; Maruna, Thomas  
**Subject:** Information Requested: BLA 125562 - Please Respond by December 19, 2014

**Importance:** High

**\*Sent on Behalf of Thomas Maruna\***

Cangene Corporation [Emergent Biosolutions]  
Attention: Ms. Allison Kennedy  
December 15, 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. Regarding the Lot Release Protocol Template submitted in 3.2.R Regional Information: Please remove 'DPQC' from the header reading "FDA-DPQC RELEASE PROTOCOL".

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 December 19, 2014.

If Cangene is unable to respond by the requested dates, 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,

**LT Tracy Tilghman, MPH, CHES**  
Lieutenant, United States Public Health Service  
Regulatory Project Manager

U.S. Food & Drug Administration  
CBER/OBRR/IOD  
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