

## Tilghman, Tracy

---

**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  
Phone: 240-402-8376  
Blackberry: 240-401-3924  
Email: [tracy.tilghman@fda.hhs.gov](mailto:tracy.tilghman@fda.hhs.gov)

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."