

From: Maruna, Thomas
Sent: Thursday, March 19, 2015 12:06 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Fisher, Robert
Subject: Request for Additional Information: BLA 125562.0 - (b) (4)

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 19, 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:

STN	Name of Biological Products
BL 125562/0	Anthrax Immune Globulin Intravenous (Human)

We have the following recommended changes to (b) (4)

1. (b) (4)

2. (b) (4)

3. (b) (4)

Please submit the revised version as soon as possible.

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)^{CM}
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
Food and Drug Administration

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