

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:

STN	Name of Biological Products
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)^{CM}
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer

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