

From: Maruna, Thomas
Sent: Tuesday, March 24, 2015 5:31 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Fisher, Robert; Mintz, Paul; Valencia, Iliana
Subject: Revised PI: BLA 125562.0 - For Your Review and Acceptance

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 24, 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 edited the PI, and are providing our final version for your review and acceptance (attached).



Please submit the final draft PI, with requested changes, to this file ASAP. [A reply to this email with the revised PI attached, in WORD and PDF; this will be sufficient.](#)

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
Center for Biologics Evaluation and Research
Office of Blood Research and Review

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