

From: Maruna, Thomas
Sent: Monday, March 23, 2015 1:22 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Fisher, Robert; Pierce, Leland Ross
Subject: BLA 125562.0 - Final PI for Review

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 23, 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).



Should you have any concerns or edits, please contact Dr. Robert Fisher directly and copy me.

Please submit the final draft PI to this file ASAP.

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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