

From: Maruna, Thomas
Sent: Tuesday, March 03, 2015 5:02 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Valencia, Iliana; Fisher, Robert
Subject: Information Requested - PMC Commitment: BLA 125562 - Please Respond by March 4, 2015

Importance: High





Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 3, 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)

Please review and commit to the following (b) (4) post-marketing commitments as discussed in the February 23, 2015 telecon:

1. Cangene commits to (b) (4)

Cangene will submit the final validation report as a PMC Study – Final report, on March 16, 2016.
2. Cangene commits to (b) (4)

submitted as a CBE-30 by March 16, 2016 and prior to the manufacture of any new lots of Anthracil.
3. Cangene commits to (b) (4)

submitted as a PMC-Final Study Report by September 16 , 2015
4. Cangene commits to (b) (4)


(b) (4)

2015

will be submitted as a CBE0 to FDA by May 16th,

Please verify that the lot numbers in PMC#4 correspond with the quarantined lots of AIGIV; if not, please substitute those in your PMC confirmation.

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 March 4, 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
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Blood Research and Review
10903 New Hampshire Ave.
Silver Spring, MD 20993
thomas.maruna@fda.hhs.gov
O: (240) 402-8454
www.usphs.gov



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