

From: Maruna, Thomas
Sent: Wednesday, September 10, 2014 1:00 PM
To: Allison Kennedy (akennedy@ebsi.com); 'smcgregor@ebsi.com'
Cc: Wernly, Claire; Fisher, Robert
Subject: Information Requested: BLA 125562/0 - Please Respond by September 26, 2014

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
September 10, 2014
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	Anthrax Immune Globulin Intravenous (Human)

We determined that the following information is necessary to continue our review:

1. Please provide the bioburden qualification report for AIGIV, showing the suitability of the test method used, conformance and recovery of inoculated microorganisms in the presence and absence of drug product (to include lot numbers), and relevant negative controls in accordance with (b) (4) and (b) (4)
2. Please provide the sterility qualification report for AIGIV showing the test was qualified in accordance with (b) (4) to confirm the product matrix for the final container drug product is suitable for the intended test method. Please include the indicator microorganisms tested, their media, conformance lot numbers, and incubation conditions used in the qualification.
3. Please provide the (b) (4) endotoxin test qualification report for AIGIV showing the drug product matrix is suitable for the intended test method (in accordance with (b) (4) to include maximal valid dilution, tested dilutions, positive product control percent recoveries, lot numbers, selected testing dilution and endotoxin test results.

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 September 26, 2014 referencing the date of this request.

If Cangene is unable to respond by September 26th, 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

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