

**From:** Maruna, Thomas  
**Sent:** Monday, March 16, 2015 10:04 AM  
**To:** Allison Kennedy (akennedy@ebsi.com)  
**Cc:** Fisher, Robert  
**Subject:** March 16, 2015 PMC Commitment Confirmation: BLA 125562

**Importance:** High

Cangene Corporation [Emergent Biosolutions]  
Attention: Ms. Allison Kennedy  
March 16, 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:

<b>STN</b>	<b>Name of Biological Products</b>
BL 125562/0	Anthrax Immune Globulin Intravenous (Human)

Please review these commitments and verify the various deadlines (especially the dates in PMC #1, #3) and the addition of PMC #9:

1. Conduct a field study (protocol AX-003A) to evaluate the efficacy, pharmacokinetics, and safety of Anthrax Immune Globulin (Human) for the treatment of toxemia associated with inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. The primary endpoint of this study will be all-cause mortality.

Final Protocol Submission: October 31, 2015

Completion of Enrollment: To be determined in consultation with FDA should a broad anthrax exposure event occur.

Completion of Data Collection: 9 months after last Anthrax Immune Globulin (Human) administration following a broad anthrax exposure event.

Study Completion: 12 months after last Anthrax Immune Globulin (Human) administration following a broad anthrax exposure event.

Final Report Submission: 15 months after last Anthrax Immune Globulin (Human) administration following a broad anthrax exposure event.

2. To periodically submit and analyze cumulative clinical and pharmacokinetic data from use of Anthrax Immune Globulin (Human) in sporadic systemic anthrax cases (protocol AX-003B).

Final Protocol Submission: October 31, 2015

Completion of Enrollment: To be determined in consultation with FDA.

Completion of Data Collection: To be determined.

Study Completion: To be determined.

Final Report Submission: 9 years after final protocol approval.

Please submit the protocols to your IND 11982, with a cross-reference letter to this BLA. Submit all final reports to this BLA as a supplemental application. For administrative purposes, all submissions related to this/these required Subpart H postmarketing studies must be clearly designated as:

- **Required Postmarketing Protocol - Subpart H Postmarketing Requirements**
- **Required Postmarketing Correspondence - Subpart H Postmarketing Requirements**
- **Required Postmarketing Final Report - Subpart H Postmarketing Requirements**

Your Subpart H studies required under 601.91(b)(1) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.70. Label your annual report an “**Annual Status Report of Postmarketing Study Requirement/Commitments.**”

## **AGREED UPON POSTMARKETING COMMITMENTS**

### **Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70.**

3. Cangene commits to (b) (4)

Manufacturing will commence pending the availability of funding for the production run(s), and this change will be submitted, with validation data, as a CBE-30 within 5 months of completion of the run(s) or by March 25, 2025, whichever is earlier.

4. Cangene commits to (b) (4)

Cangene will submit the final validation report as a Postmarketing Study Commitment – Final Study Report by March 16, 2016.

5. Cangene commits to developing (b) (4) [REDACTED] submitted as a CBE-30 by March 16, 2016, and will be applicable to any new lots of Anthrax Immune Globulin (Human) manufactured after you are notified that this PMC is fulfilled.

6. Cangene commits to (b) (4) [REDACTED] Postmarketing Study Commitment – Interim Study Report by September 16, 2015. If the initial assessment is supportive, a complete assessment that includes supportive stability data will be submitted as a Postmarketing Study Commitment – Final Study Report by March 16, 2016.

7. Cangene commits to (b) (4) [REDACTED] will be submitted as a CBE-30 to FDA by May 16, 2015.

8. Cangene commits to (b) (4) [REDACTED] will be submitted as a CBE by March 25, 2016.

9. Cangene commits to submitting a request for exemptions or alternatives to labeling requirements for biological products held by the Strategic National Stockpile per 21 CFR 610.68. This request will include specific lot numbers, the labeling provisions that are the subject of the exemption or alternative request, an explanation why compliance with the labeling regulations could impact the safety, effectiveness, or availability of AIGIV, a description of proposed safeguards to ensure the labeling of the product conveys adequate information for the safe and effective use of the product, and a draft of the proposed labeling. Cangene will submit this information as a CBE30 by April 25, 2015.

**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.

**You may verify these commitments and proposed dates by responding to this email by March 17, 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)<sup>CM</sup>

Lieutenant, U.S. Public Health Service

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