

From: Maruna, Thomas
Sent: Wednesday, November 05, 2014 12:46 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Fisher, Robert; Wang, Yonggang; Wernly, Claire; Tilghman, Tracy (Tracy.Tilghman@fda.hhs.gov)
Subject: Information Requested: BLA 125562 - Please Respond by November 14 & November 17, 2014

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
November 5, 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:

Bioburden, Sterility and Endotoxin – Due November 17, 2014

1. In order to comply with (b) (4) CBER finds (b) (4) Method Suitability Test Report (STM 500114) (QCM_MS_0021_rep_v1) for bioburden test of (b) (4) incomplete since it does not include an evaluation of (b) (4) . Please provide comparable data (to include lot numbers and relevant negative controls) for indicator microorganisms and sample controls to include the use of (b) (4) .
2. In addition, as per (b) (4) unless otherwise directed, (b) (4) . According to the (b) (4) Suitability Test Report (STM 500114) (QCM_MS_0021_rep_v1) (b) (4) CBER finds this sample volume to be under representative of the required test volume as per (b) (4) . Please provide comparable data (to include lot numbers and relevant negative controls) using the entire (b) (4) .

CMC – Due November 14, 2014

3. There is a formatting issue with the page 30 in your file of STM 500206, where the text was overlaid and covered by a graph. Please correct the error and provide an updated file.
4. Please specify the (b) (4) being used in your (b) (4) potency assay.
5. A (b) (4) was qualified to be used in STM 501016, but it was not used in STM 520127. Please explain why a (b) (4) is not necessary in STM 520127, although the same type of (b) (4), i.e., (b) (4), are used in both STM 501016 and STM 520127 methods. In addition, please indicate (b) (4) has been defined, if not, please provide your justification.
6. Please predict when the legacy method STM501016 will be replaced by the new method STM 520127, and estimate the impact of this method change on your ongoing stability studies.
7. Please provide the following documents:
 - a. Cangene Method Validation Addendum # B53-A Report.
 - b. Method Validation No. MV_034 for method STM 501500.
 - c. Method Validation No. MV_0152 for method STM 500173.
 - d. Method Validation No. MV_0160 for method STM 520033.

Lot Release Protocol – Due November 17, 2014

8. The lot release protocol included in your BLA for Anthrax Immune Globulin Intravenous (Human) appears to be that used for Varicella Zoster Immune Globulin (Human). Please submit the actual protocol to be used for Anthrax Immune Globulin Intravenous (Human). If different versions of the lot release protocol have been used to release product to the SNS, please submit a copy of each version as well as a table identifying which lots were released with each version of the protocol.

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 as indicated above referencing the date of this request.

If Cangene is unable to respond by the requested dates, 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}

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