

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Wednesday, November 26, 2014 3:14 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Maruna, Thomas
Subject: Information Requested: BLA 125562/0 - Please Respond by December 5, 2014

Importance: High

Sent on behalf of Thomas Maruna

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
November 26, 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:

Regarding the following TNA Method Validation Reports:

1. Toxin Neutralization Assay (TNA for Quantification of Anthrax Immune Globulin (AIG) in Non-Clinical Monkey Serum Samples
2. Toxin Neutralization Assay (TNA for Quantification of Anthrax Immune Globulin (AIG) in Non-Clinical Rabbit Serum Samples
3. Toxin Neutralization Assay (TNA for Quantification of Anthrax Immune Globulin (AIG) in Clinical Human Serum Samples
4. Antrax Toxin Neutralization Assay (TNA) for Potency Determination of (b) (4) Purified Immunoglobulin Test Articles

You have analyzed the raw data for the precision studies in these four reports using the statistical methods described in DeSilva et al (Desilva B, et al, Pharm Res. 2003; 20:1885-1900). However, log-transformation is recommended in more recent guidance documents, such as USP bioassay chapters, and is recognized as the standard and appropriate analysis scale in assay validation and PK studies. Please reanalyze the data for the precision studies using a log-transformation.

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 December 5, 2014 referencing the date of this request.

If Cangene is unable to respond by December 5, 2014, please propose an alternative date to respond.

The action due date for these files is March 25, 2015.

If you have any questions, please contact me.

Very Respectfully,

LT Tracy Tilghman, MPH, CHES

Lieutenant, United States Public Health Service

Regulatory Project Manager

U.S. Food & Drug Administration

CBER/OBRR/IOD

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