

From: Maruna, Thomas
Sent: Tuesday, August 26, 2014 12:06 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: King, Colonious
Subject: Information Requested: BLA 125562/0 - Please Respond By September 9, 2014

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
August 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:

Clinical

1. The PMR protocol synopsis (AX-003) was submitted under the Pharmacovigilance Plan folder in Module 1 and not with the clinical information in Module 5. Please resubmit this protocol synopsis under the clinical module (5).
2. For clinical study AX-001, we are unable to locate the Data definitions for the three data sets (BLD, PKC, and PKP) under the Data listing Data folder in section 5.3.3, reports of Human Pharmacokinetic (PK) studies. Please submit the data definitions for these data sets.

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 9, 2014 referencing the date of this request.

If Cangene is unable to respond by September 9th, 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

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