

From: Maruna, Thomas
Sent: Wednesday, October 01, 2014 2:35 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Mahmood, Iftekhar; Fisher, Robert; Haddad, Salim A
Subject: Information Requested: BLA 125562/0 - Please Respond By October 8, 2014

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
October 1, 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 AUC (0-7 days) and AUC (0-14 days) values for healthy human subjects, normal rabbits and monkeys for each dose and associated clearance values calculated based on these partial AUCs.
2. Please provide the AUC (0-14 days) values for rabbits in (study 1207-100005104) and associated clearance values calculated based on this partial AUC. Please confirm that the reported clearance in study 1207-100005104 for AUC (0-7) is correct for both (b) (4) and TNA assays.
3. Please provide the pharmacokinetic parameters related to the 'impact of immunogenicity on the pharmacokinetics of NP-015' in rabbits and monkeys from the studies from which such data are available.
4. Please combine males and females PK data (b) (4) Study No. 658-G005681) and report the mean and standard deviation for the PK parameters.

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 October 8, 2014 referencing the date of this request.

If Cangene is unable to respond by October 8th, 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

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