

Valencia, Iliana

From: Valencia, Iliana
Sent: Tuesday, January 20, 2015 7:52 AM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)
Subject: STN125562 Anthrax Immune Globulin Intravenous (Human): Information Request (IR)

Our Reference: BL125562

Cangene Corporation
Attention: Allison Kennedy
January 20, 2015
Sent by EMAIL

Dear Ms. Kennedy:

We are reviewing your July 25, 2014 biologics license application (BLA) for Anthrax Immune Globulin Intravenous (Human). We request are requesting the following information:

Please submit a table summarizing the available PK data for AIGIV acquired from healthy human subjects and both healthy and anthrax-infected non-human primates and rabbits. In particular, provide a comparison of the AUC0-7 days, AUC0-14 days, and AUC0-infinity for each of these species/conditions.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for this file is March 25, 2015.

Please submit a response as an amendment to the file by January 30, 2015.

If you have any questions, please contact me.

Sincerely,

Iliana Valencia on behalf of Thomas Maruna.

Iliana Valencia, MS
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IOD
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