

From: Maruna, Thomas
Sent: Friday, October 03, 2014 12:23 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: smcgregor@ebsi.com; Fisher, Robert; Pierce, Leland Ross
Subject: Information Requested: BLA 125512/0 - Please Respond by October 24, 2014

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
October 3, 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 summarize and submit electronic line listings and SAS transport file datasets for pediatric safety data for pediatric patients administered your Varicella Zoster Immune Globulin (Human) and Rh0(D) Immune Globulin Intravenous (Human) products. Please discuss the rationale, pros, and cons of extrapolating safety in pediatric subjects who received these immunoglobulin product(s) to pediatric patients who would receive your AIGIV product. We note that you propose an indication in both adults and pediatric patients, yet you have provided no safety data for your product in the pediatric population. The only clinical trial you conducted with the product, AX-001, enrolled healthy subjects ages 19 to 55 years and the patients with systemic anthrax to whom your AIGIV product was administered on a compassionate use basis for whom you submitted safety data were ages 24 to 61 years.
2. Review of urinalysis data from AX-001 indicates a finding of dose-related glycosuria on day 1 following infusion of the active product. Please modify the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections of the full prescribing information of the draft package insert to reflect this information. In addition, please determine whether the test strips used for urinalysis in the trial mistake maltose for glucose.

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 24, 2014 referencing the date of this request.

If Cangene is unable to respond by October 24th, 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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