

From: Maruna, Thomas
Sent: Tuesday, March 03, 2015 2:36 PM
To: Allison Kennedy (akennedy@ebsi.com)
Cc: Pierce, Leland Ross; Fisher, Robert
Subject: Information Request: Cangene BLA 125562.0 - Please Respond by March 6, 2015

Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 3, 2015
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 125562/0	Anthrax Immune Globulin Intravenous (Human)

We determined that the following information is necessary to continue our review:

1. Please provide the target date(s) prior to the ADD for this application by which you expect to submit the full draft protocols for PMR studies AX-003a and AX-003b.
2. Please confirm, pursuant to the discussion during the teleconference with FDA held Monday 23 February 2015, that you agree, for study AX-003A, to conduct a comparison of the mortality rate observed in that study to the mortality observed among patients with inhalation anthrax observed during the 2001 U.S. anthrax incident, providing there are sufficient similarities between the two data sets in the demographics, extent of pre-existing co-morbidities, time between onset of symptoms and initiation of treatment with antibiotics, and whether the antibiotic treatments are initiated in the prodromal stage or in the fulminant stage in the patients in the two datasets .

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 March 6, 2015.

If Cangene is unable to respond by the requested date, 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

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.