

From: Maruna, Thomas  
Sent: Tuesday, March 10, 2015 4:42 PM  
To: Allison Kennedy (akennedy@ebsi.com)  
Cc: Scott, Dorothy; Fisher, Rob  
Subject: Amendment Requested: (b) (4) - Please  
Respond by  
March 12, 2015

(b) (4) (b) (4)

Importance: High

Cangene Corporation [Emergent Biosolutions]  
Attention: Ms. Allison Kennedy  
March 10, 2015  
Sent by email

Dear Ms. Kennedy:

We are reviewing your July 25, 2014 biologics license application (BLA) indicated for the treatment of toxemia associated with inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs for the following:

STN	Name of Biological Products
BL 125562	Anthrax Immune Globulin
Intravenous (Human)	

(b) (4)

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If Cangene is unable to respond by March 12th, please propose an alternative date to respond.

The action due date for these files is March 25, 2014.

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  
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