

From: Allison Kennedy <akennedy@ebsi.com>
Sent: Tuesday, March 24, 2015 6:06 PM
To: Maruna, Thomas
Cc: Fisher, Robert; Mintz, Paul; Valencia, Iliana
Subject: RE: Revised PI: BLA 125562.0 - For Your Review and Acceptance
Attachments: aig-prescribing-information-word-cangene.pdf; aig-prescribing-information-word-cangene.DOCX; emfinfo.txt

Hello Thomas,

Please see attached final draft PI, in which Cangene have accepted all proposed changes. Both a word and a PDF version are included as attachments to this email. This information will also be submitted through the gateway.

Best Regards,

Allison

From: Maruna, Thomas [mailto:Thomas.Maruna@fda.hhs.gov]
Sent: Tuesday, March 24, 2015 4:31 PM
To: Allison Kennedy
Cc: Fisher, Robert; Mintz, Paul; Valencia, Iliana
Subject: Revised PI: BLA 125562.0 - For Your Review and Acceptance
Importance: High

Cangene Corporation [Emergent Biosolutions]
Attention: Ms. Allison Kennedy
March 24, 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 have edited the PI, and are providing our final version for your review and acceptance (attached).

Please submit the final draft PI, with requested changes, to this file ASAP. A reply to this email with the revised PI attached, in WORD and PDF; this will be sufficient.

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.