

Valencia, Iliana

From: Valencia, Iliana
Sent: Sunday, January 25, 2015 9:49 PM
To: Allison Kennedy (akennedy@ebsi.com)
Subject: STN125562 Anthrax Immune Globulin Intravenous (AIGIV): Labeling comments
Attachments: aig-prescribing-information-word_Jan25 edits.docx

Our Reference: BL 125562/0

Dear Ms. Kennedy:

I am conveying the attached labeling comments and recommendations for Cangene's Anthrax Immune Globulin Intravenous (AIGIV) BLA.

Please submit your response to this information request as an amendment to this file by February 2, 2015 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

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

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