

Valencia, Iliana

From: Valencia, Iliana
Sent: Monday, February 02, 2015 10:09 AM
To: Allison Kennedy (akennedy@ebsi.com)
Subject: STN125562 Anthrax Immune Globulin Intravenous (Human): labeling review
Attachments: aig-prescribing-information-word_2-2-15.docx

Importance: High

Our Reference: BL125562

Cangene Corporation
Attention: Allison Kennedy
February 2, 2015
Sent by EMAIL

Dear Ms. Kennedy:

We are reviewing your July 25, 2014 biologics license application (BLA) for Anthrax Immune Globulin Intravenous (Human). Attached are the 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 referencing this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format.

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

If you have any questions, please contact me.

Sincerely,

Iliana Valencia, MS
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IOD
240-402-8444
202-591-6054
iliana.valencia@fda.hhs.gov

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