

Valencia, Iliana

From: Valencia, Iliana
Sent: Tuesday, January 13, 2015 8:45 AM
To: 'akennedy@ebsi.com'
Cc: Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)
Subject: STN125562 Anthrax Immune Globulin Intravenous (Human): FDA Request

Our Reference: BL125562

Cangene Corporation
Attention: Allison Kennedy
January 13, 2015
Sent by EMAIL

Dear Ms. Allison:

We are reviewing your July 25, 2014 biologics license application (BLA) for Anthrax Immune Globulin Intravenous (Human). We request that you make the following postmarketing commitments:

1. Cangene commits to (b) (4) [REDACTED] This change will be submitted, with validation data, as a CBE-30 by March 25, 2016.
2. Cangene commits to (b) (4) [REDACTED] The validation report will be submitted to CBER as a CBE-30 by March 25, 2016.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

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

Please send an acknowledgement for receipt of this request. And submit a response as an amendment to the file by January 26, 2015.

If you have any questions, please contact me.

Sincerely,

Iliana Valencia on behalf of Thomas Maruna.

Iliana Valencia, MS
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IOD
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