

From: Tilghman, Tracy
To: [Allison Kennedy \(akennedy@ebsi.com\)](mailto:akennedy@ebsi.com)
Cc: [Maruna, Thomas](#)
Subject: Reference BL 125562/0 - Information Request
Date: Tuesday, December 23, 2014 6:23:00 PM
Importance: High

Our Reference: BL 125562/0

Dear Ms. Kennedy:

I am conveying the following comments for Cangene's Anthrax Immune Globulin Intravenous (AIGIV) BLA on behalf of LT. Thomas Maruna.

1. Please provide the bulk product storage time for individual AIGIV lots for which the (b) (4) has been retested, i.e., all the lots shown in your table 1: Conversion of (b) (4) (Table 1 contained in your information request response of November 10, 2104).
2. The stability study 250195-02 was executed to support a maximum (b) (4). However the tested sample (time 0) was taken prior to regular storage at (b) (4). This condition will not represent the real condition of up to (b) (4) storage time at (b) (4) before filling takes place. Since this temperature excursion validation also included your other Hyperimmune products, i.e., WinRho and HepaGam B, please indicate if the same procedure has been successfully validated in these products and represents the real situation of storage prior to filling. Please reference the relevant data in your response to this information request.
3. Regression analysis predicted for Lot (b) (4) (filled on 09/24/2010) a failure time of 66 months for (b) (4). Please provide the investigation report for this event, and repeat the (b) (4) test. Please consider adding test timepoints to this lot into full testing stability study until a root cause has been identified or the predicted failure time based on new data is greater than 72 months. Please provide the new testing data to CBER for review no later than Feb 20, 2015.

Please submit your response to this information request as an amendment to this file by December 30, 2014 referencing the date of this request. 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.

If you have any questions, please let me know.

Sincerely

LT Tracy Tilghman, MPH, CHES
Lieutenant, United States Public Health Service
Regulatory Project Manager

U.S. Food & Drug Administration
CBER/OBRR/IOD
Phone: 240-402-8376
Blackberry: 240-401-3924
Email: tracy.tilghman@fda.hhs.gov

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