



MEMORANDUM

Date: 06 January, 2015

From: Karen Campbell and Josephine Resnick, Ph.D.
Regulatory Coordinators
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: **Biologics License Application Submission Tracking Number # 125562/0**

Subject: **Review of Lot Release Protocol Templates for Drug Substance and Drug Product of Biologics License Application for Anthrax Immune Globulin Intravenous (Human)**

Through: William M. McCormick, Ph.D., Director, DBSQC/OCBQ/CBER/FDA

Cc: Thomas Maruna, RPM,
Robert Fisher, Chair,

Applicant: Cangene Corporation

Product: Anthrasil™, Anthrax Immune Globulin Intravenous (Human) [AIGIV]

Background

On July 25, 2014, Cangene Corporation submitted a Biologic License Application for Anthrasil™, Anthrax Immune Globulin Intravenous (Human) [AIGIV]. The draft lot release protocol template submitted in 3.2.R of the original application was reviewed by the Division of Biological Standards and Quality Control (DBSQC), and the Product Release Branch. Comments were sent to Cangene on November 17, 2014 and a revised lot release protocol template was received in amendment 125562/0.14 on December 1, 2014. This amended template was reviewed by DBSQC and the Division of Hematology, and no issues were identified.

Submissions Reviewed in this Memo

125562/0.0 Lot Release Protocol Template in section 3.2.R.
125562/0.14 Lot Release Protocol Template in section 3.2.R.
125562/0.18 Lot Release Protocol Template in section 3.2.R.

Conclusion:

The lot release protocol template submitted in 125532/0.14 (received December 1, 2014) is acceptable for use with (b) (4) and will be reviewed to effect lot release at licensure. Cangene will edit the lot release protocol after licensure, as needed for future lots.

Review:

Cangene Corporation submitted a lot release protocol template in the original application: 125562/0.0 on July 25, 2014. Comments were sent on November 17, 2014, and a revised lot release protocol was submitted on December 1, 2014. This template was reviewed, and one additional request was submitted to the sponsor on December 15, 2014. The sponsor addressed our comment and submitted a revised lot release protocol template on December 16th. This protocol template was reviewed and no issues were identified. This protocol has been approved by CBER for future lot release submissions. Comments and CBER's review of responses and conclusions are shown below. CBER's conclusions are shown in **bold font**.

Comments sent in an IR dated November 17, 2014:

1. On page 1, Please change the title of the product from "Varicella Zoster Immune Globulin (Human)" to "Anthrax Immune Globulin Intravenous (Human)"
2. On page 2, there are spelling errors, Anti-A Haemagglutinis' and 'Anti-B Haemagglutinis' needs to be changed to: 'Anti-A Hemagglutinins' and 'Anti-B-Hemagglutinins'
3. On page 5: Sterility, please add the method type, for example: (b) (4)
4. On page 5: Sterility, Please add the (b) (4) test date.

5. The sterility test qualification was carried out using (b) (4) vials/media type, which relates to (b) (4) vials for 'tested quantity'. On page 5: sterility, (b) (4) vials are shown for 'tested quantity'. Please confirm that (b) (4) vials will be used, and clarify this discrepancy. .

Comments sent in an IR dated December 15, 2014:

Regarding the Lot Release Protocol Template submitted in 3.2.R Regional information: Please remove 'DPQC' from the header reading "FDA-DPQC RELEASE PROTOCOL".

Conclusion: Responses submitted to CBER for both IRs, along with a revised lot release protocol template in amendment 125562/0.18 on December 16, 2014 are acceptable for future lot release submissions.