
Report of Telephone Conversation

Date/Time of Call: October 31, 2014 at 11:00am

CBER Representative: Randa Melhem, PhD, OCBQ/DMPQ

Organization Representatives: Allison Kennedy, M.Sc, RAC, Manager, Regulatory Affair Biosciences Division

Organization: Cangene Corporation

Telephone: 204-275-4530

Subject: Information Request

STNs: 125562/0

Cangene Corporation (Cangene) doing business as (dba) Emergent BioSolutions submitted this BLA to provide information to support US market authorization of Anthrax Immune Globulin Intravenous (Human) [AIGIV] presented as a sterile frozen liquid in single dose 50mL vials.

During the review of the Batch Records, I noted that several sections were redacted (blacked-out). I asked Ms. Kennedy the justification for the redactions. She said she will check it out.

She responded by email (31 Nov 2014) stating that *“Current practice is to redact information that is in support of other products/lots, etc... and is not pertinent to the lot specific batch record, given that samples from numerous lots may be batched for testing. The original QC report is not redacted – only the copy of the assay that is put in the lot specific batch record”*.

In addition I requested more information about the visual inspection of the AIGIV drug product.

- Please provide a validation of the visual inspection (VI) process used for the AIGIV liquid final product presentations. In addition, please provide the VI procedure and describe in detail the critical, major and minor defects, and the acceptance criteria of each for the batch to pass visual inspection.
- Please provide the AQL procedure, and the acceptance criteria for accepting or rejecting a batch.

The additional information about the visual inspection will be provided with the submission of responses to the 13Oct IR, targeted for Monday 03 Nov 2014.
