

Lot Release Meeting, November 9, 2012 - Novoeight

125466/0 – Lot Release Meeting

November 9, 2012

Attendees:

Roman Drews (RD) – Chair/CMC/Product reviewer
Andrey Sarafanov—CMC/Product
Leigh Pracht—RPM
Lokesh Bhattacharyya (LB)-Lab chief (Laboratory of Analytical Chemistry and Blood Related Products)
Karen Campbell (KC)—Regulatory coordinator
Catherine (Katie) Poole – Regulatory coordinator
Al Del Grosso – Chemistry testing

Not Present (Cc :)

James Kenney (JK) – Sterility and endotoxin testing
Kori Francis (KF) – Potency testing

Purpose/Goals:

- In-support Testing requirements

Summary of Product and Proposed Indication

- The proposed indication for Novo Nordisk's Antihemophilic Factor (Recombinant), Plasma/Albumin-Free [NovoEight], is the control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults, adolescents and children with hemophilia A. As a recombinant protein this will most likely be exempt from lot release post licensure.

Discussion

General Discussion

- As a recombinant protein this will be exempt from lot release. The only exceptions will be if there is a lack of history with the specific product or we fail to get similar potency results in the CBER labs.
- Since it will most likely be exempt from lot release, no lot release protocol will be requested and samples should be sent directly to the labs (to Karen Campbell or Katie Poole).

- Since this BLA has come in under PDUFA V KC requested that DBSQC reviewers look over the BLA submission and let her know if any important documents needed for review were missing. Jim Kenney indicated that the DS validation/qualification reports for -----(b)(4)----- and the DP validation/qualification reports for sterility and endotoxin had not been submitted. KC will forward this information to Roman.

Support Testing

- The applicant has produced consistency lots which we will request for testing. There are 6 dosages of this product; 250, 500, 1000, 1500, 2000 and 3000 IU of Antihemophilic Factor.
- We agreed that we would test one lot from each of 3 dosages, 250, 1000, and 3000 IU/vial
- The team decided to perform the following in-support testing:
 - Appearance of powder, reconstitution time and appearance of solution
 - Water content by Karl Fischer Coulometry; this is also being tested by (b)(4). The validation of the (b)(4) will be reviewed by someone in AI's group.
 - Potency by the ATPP (one stage clotting) assay for information only –this is not the test performed by Novo Nordisk. This is the test that hospitals use and will be of value to know how closely the results from this test match the results of the chromogenic assay that Novo Nordisk is using for their label values.
 - Purity and -----(b)(4)-----
 - Content and -----(b)(4)-----
 - Endotoxin
- Sterility will not be tested; Roman and Tim Lee have discussed sterility testing of these recombinant products and have decided that it will not be required because of the cost of so many units and that the applicant has a good track record with these types of products.
- DBSQC will get information on how many samples to request and any information or reagents needed by COB on Wednesday, November 28.

Action Items

- AI, Lokesh, Jim and Kori will put information/reagent requests together and submit them to KC before Nov 28.
- KC will send the RPM and chair the request for samples by Nov 28 and a draft of the testing plan by the mid cycle.
- When samples have arrived DBSQC (KC) will notify the chair and RPM of the expected completion dates of the testing.
- KC to send Roman the information on the missing validation/qualification reports
- AI will assign someone in the Chemistry group to perform a consult review of the validation of the (b)(4) method for water content.

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