

Information Request Letter - Novoeight

Dear Dr. Cao:

We are reviewing your Biologics License Application (STN 125466) for Antihemophilic Factor (Recombinant) [NovoEight] submitted on October 15, 2012. We are requesting the following additional information to continue our review:

1. Please submit nine vials for each of the Process Performance Qualification lots of Drug Product: ---(b)(4)--- (250 IU), ---(b)(4)--- (2000 IU), and --(b)(4)-- (3000 IU). In addition, please submit three vials for each of the following lots of Drug Product: - (b)(4)-- (250 IU), --(b)(4)-- (1000 IU), -(b)(4)- (2000 IU).

2. With regard to Analytical Procedure Y9-435 "*Identity and Purity* ---(b)(4)---" (novoDOCS ID 001203897), please provide:

a) Reference material (Section 6) - current NovoEight Reference material

b) Control material (Section 7) – "suitable sample type of drug substance or drug product" as cited.

c) Section 5.2 "------(b)(4)-----
-----". Please provide the manufacturer and part number for this -----(b)(4)----- . Please indicate if a ----(b)(4)---- or any other accessories are used.

3. With regard to Analytical Procedure M042, "*Content and* -----(b)(4)-----" (novoDOCS 001205523), please provide the following:

a) Reference material (Section 5) – current NovoEight Secondary Reference Material (SRM)

b) Control material (Section 6) - "suitable sample type of drug substance or ... drug product" as cited

c) Section 4.2 Equipment / -----(b)(4)----- are cited, a -----
-(b)(4)----- . Please indicate if -----(b)(4)----- types have been fully validated for this procedure and if -----(b)(4)----- has been used for the analysis of the samples to be submitted in support of this application. Please also indicate if ---
(b)(4)--- or other accessories are used in addition to the -----(b)(4)-----

4. With regard to Analytical Procedure Y9-440 "*FVIII activity by One-stage clotting assay*" (novoDOCS id:001216331), please provide the following:

- a) Reference material (Section 6) – current NovoEight Secondary Reference Material (SRM)
- b) Control material (Section 8) – samples of drug substance and/or samples of drug product
- c) Drug product reconstitution buffer (0.9% Sodium Chloride) and sample dilution buffer (---(b)(4)---)

Please submit all the referenced above materials to the address provided below:

Karen Campbell
Regulatory Coordinator (DBSQC)
OCBQ/CBER/FDA
Building B - Room 2410
5516 Nicholson Lane
Kensington, MD 20895

Please contact Karen via email at karen.campbell@fda.hhs.gov or via telephone at 301-594-6255 prior to sample submission to alert CBER that the samples are being sent. The drug product samples should be labeled with the STN and lot number at a minimum. The name of the manufacturer and date of manufacture can be on the label or the associated paperwork.

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

Please submit your responses to this information request by December 21, 2012 referencing the date of this request. Please email me when you have shipped these samples. 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.

If you have any questions, please contact me.

Page Last Updated: 01/28/2015

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