

Information Request, March 27, 2013 - Novoeight

Our Reference: BL125466/0

Novo Nordisk Inc.
Attention: Cindy Cao, PhD
March 27, 2013
Sent by email

Dear Dr. Cao:

We are reviewing your October 16, 2012 biologics license application (BLA) for Antihemophilic Factor (Recombinant), Plasma/Albumin Free [NovoEight]. We are providing the following comments and request for additional information to continue our review:

1. Please provide detailed information on -----(b)(4)----- procedure before the -(b)(4)-- can be used to perform the assay, such as the number of -----(b)(4)-- ----- and the acceptance criteria to ensure that the ----- (b)(4)----- has been achieved.
2. What are the criteria to differentiate between the -----(b)(4)----- Please explain how the -----(b)(4)----- can be calculated objectively and reproducibly.
3. You have used a -----(b)(4)----- for the determination of the -----(b)(4)- ----- of the product, for which the ----(b)(4)--- of the standard and the sample should be close. However, the ----(b)(4)----- obtained using the Analytical Procedure M042 is about -----(b)(4)----- than that of 250 IU dosage and about ----(b)(4)-- that of 2000 IU dosage. Please explain why -----(b)(4)----- method is acceptable for these two dosages.
4. Please provide ----(b)(4)---- details, including -(b)(4)-- cleaning and storage procedure after the assay is completed.

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 response to this information request as an amendment to this file by April 4, 2013 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 October 16, 2013.

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh Pracht
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB

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