

Information Request Letter, September 9, 2013 - Novoeight

DEPARTMENT OF HEALTH & HUMAN SERVICES
Service

Public Health

Food and
Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Our Reference: BL125466/0

Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
September 9, 2013
Sent by email

Dear Dr. Pollack:

We are reviewing your October 15, 2012 biologics license application (BLA) for Antihemophilic Factor (Recombinant) [Novoeight]. We determined that the following information is necessary to continue our review:

1. Please revise the SOP for the analytical method M042 "Determination of ----- (b)(4)----- and quantitative content of turoctocog alfa by ---(b)(4)---" to include:
 - a. The requirement to perform the qualification of new ---(b)(4)--- through ----- (b)(4)----- followed by testing for system suitability criteria;
 - b. The use of an objective automatic approach for -----(b)(4)----- using your -(b)(4)-system software;
 - c. Description of the details of performing the assay which are critical for the outcome, based on your Visit Report (Amendment dated August 20th, 2013) and comments from DBSQC (the file is attached for your consideration);
 - d. Please submit to the BLA file the updated version of the analytical procedure M042 based on the revised SOP, and with the corrected carry-over acceptance criterion.

If the SOP is revised to assure consistence performance of the assay, the FDA will consider the method acceptable, and the substantive issue resolved satisfactorily.

2. Please confirm the following Post-Marketing Commitment:

Novo Nordisk commits to develop the methods for quantitative measurement of excipients calcium chloride and sucrose in the Final Drug Product, and include these parameters with acceptance criteria in Drug Product Specification. The results will be submitted as PMC Submission – Final Study Report by [the date].

3. In Drug Product Specification, please include the parameter Potency (Factor VIII activity) determined by the One-Stage Clotting (OC) assay, in addition to Potency determined by the Chromogenic Substrate (CS) assay. For product distribution, please include both actual values of FVIII activity on the carton and vial. At this stage of scientific knowledge and clinical experience with the two assays world-wide, such approach will allow Novo Nordisk and FDA to prospectively monitor the consistency of the OC/CS ratio or any trends with the future batches of Novoeight, and offer comprehensive information to the end-users.

Please find comments from DBSQC pertaining to the Novo Nordisk Visit to FDA (August 12 – 16, 2013) attached to this information request as a separate document.

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 September 19, 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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