

Information Request, August 5, 2013 - Novoeight

Our Reference: BL125466/0

Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
August 5, 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. Qualification of the Lyophilizer (---(b)(4)--- Facility)

In your responses to comments 14, 15 and 16 (Information Request dated June 18, 2013), you did not provide data to demonstrate that all products lyophilized on all (b)(4) shelves met the acceptance criteria. You stated that in the initial qualification (temperature mapping) you monitored the temperature in a -----(b)(4)----- . In addition, you stated that in the (b)(4) verification studies, you sample every shelf --- (b)(4)--- of the loaded chamber. Please provide summary of the data to demonstrate that all products lyophilized on all shelves meet the acceptance criteria for ----- (b)(4)-----.

2. Specification for Lyophilization stopper

Please justify the specification of (b)(4) lyophilization stopper for turoctocog alfa drug product considering the vendor states it is endotoxin free.

3. Lyophilization/visual inspection

In your response to comment 19 (Information Request dated June 18, 2013), you provided information for verification of (b)(4) instead of (b)(4). Also, you stated that the 190 “other errors” were Lyo-cake non-critical errors, so why were they labeled as “other errors” and not included in the “Lyo-cake non-critical” errors. Please explain.

4. Sterilization studies (Vetter)

You reported in Document 5021235, Summary -----(b)(4)-----, that requalification of the sterilization in -----(b)(4)----- included ----- (b)(4)----- . In the report the -----(b)(4)----- study was performed in September, 2012, while the -----(b)(4)----- were performed earlier (July 2012). Please justify the time line.

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 August 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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