

Mid-cycle comments and IR Email, April 24, 2013 - Novoeight

From: Pracht, Leigh
Sent: Wednesday, April 24, 2013 1:09 PM
To: 'lew@novonordisk.com'
Subject: STN 125466/0 Post mid-cycle communication comments and request for additional information
Our Reference: BL 125466/0
Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
April 24, 2013
Sent by email

Dear Dr. Pollack:

We are reviewing your October 15, 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. Regarding the list of raw material/ingredients used in the manufacturing process of turoctocog alfa drug substance/drug product (item 5 of the Mid-Cycle communication report): FDA expects that companies develop and follow their prioritization approach in risk assessment, such as assessment of potential risk to the patient. Please provide information on the suppliers/manufacturers of potential risk materials, and indicate the stage of the manufacturing process where they are used. This request was discussed during Pre-License Inspection (PLI) of the -(b)(4)- manufacturing facility ----(b)(4)-----
--. Please submit this information as an amendment to the BLA file by June 1st, 2013.

2. Regarding additional viral clearance validation studies using -----(b)(4)-----
----- (item 4 of the Mid-Cycle communication report): as this comment relates to the April 9th Information Request (comment 6), in your response (due on May 13th, 2013) please indicate the tentative date of completing these studies.

3. Additional Information Requests pertaining to in-support testing by FDA:

a. As discussed during the PLI, the dilution factor in Endotoxin testing is (b)(4) (not (b)(4) as stated in the BLA). Please re-submit the corrected values for Endotoxin levels for the PPQ batches as part of response to comment 3 of the April 9th Information Request (due on May 13th, 2013).

b. You provided the potency value for *N8 Second. Ref. Material, Batch:* ----(b)(4)----- for the Chromogenic Assay: ---(b)(4)----. Please provide the potency value for this standard for the Clotting Assay as soon as possible by e-mail.

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 as amendments to this file by the dates requested above, referencing the date of this request. If you anticipate you will not be able to respond by these dates, please contact the Agency immediately so new response dates can be identified.

The action due date for this file is October 15, 2013.

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

Sincerely,

Leigh A. Pracht

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