

Information Request, December 3, 2012 - Novoeight

Our Reference: BL 125466/0

Novo Nordisk Inc.
Attention: Cindy Cao, PhD
December 3, 2012
Sent by email

Dear Dr. Cao:

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

1. In the BLA submission (Manufacturer section), you have provided a general overview of the facilities as relates to production of NovoEight. Please provide in a Table format detailed description of the operations performed in each of the Buildings/Facilities for both Novo Nordisk -(b)(4)-.

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 December 13, 2012 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 15, 2013.

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

Sincerely,

Leigh A. Pracht
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