

Information request Email, August 15, 2013

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From: Pracht, Leigh
Sent: Thursday, August 15, 2013 11:14 AM
To: 'LEWP (Lewis Pollack)'
Subject: STN 125466/0 Information request 08152013
Attachments: STN125466_draft-pi-text.doc

Importance: High

Our Reference: BL 125466/0

Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
August 15, 2013
Sent by email

Dear Dr. Pollack:

We are reviewing your October 15, 2012 biologics license application (BLA) for Antihemophilic Factor (Recombinant) [NOVOEIGHT]. We are providing the following comments and request for additional information to continue our review:

1. We have reviewed the package insert and request changes be made in accordance with the attached MS Word 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 by August 23, 2013 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. 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.

Best regards,

Leigh A. Pracht
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