

Information Request Email, May 13, 2013 - Novoeight

From: Pracht, Leigh

Sent: Monday, May 13, 2013 2:20 PM

To: LEWP (Lewis Pollack)

Subject: STN 125466/0: Information Request 13-May-13

Our Reference: BL 125466/0

Novo Nordisk Inc.

Attention: Lewis Pollack, PhD

May 13, 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 determined that the following information is necessary to continue our review:

1. CBER requires the following reagents and samples to complete in-support testing:

2 vials of control ---(b)(4)---

2 vials of each: -----(b)(4)----- and ---(b)(4)---

Please send them to:

Karen Campbell

DBSQC/OCBQ/CBER/FDA

Building B Room 2410

5516 Nicholson Lane

Kensington, MD 20895

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 provide shipping information, as a written amendment to this file, by May 27, 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 15, 2013.

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

Sincerely,

Leigh A. Pracht

Regulatory Project Manager

FDA/CBER/OBRR/DBA

WOC1; RM562N; HFM-380

1401 Rockville Pike

Rockville, MD 20852

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