

Information Request Email, April 22, 2013 - Novoeight

From: Pracht, Leigh
Sent: Monday, April 22, 2013 11:05 AM
To: 'lew@novonordisk.com'
Subject: STN 125466/0 Information Request
Our Reference: BL 125466/0
Novo Nordisk Inc.
Attention: Lewis Pollack, PhD
April 22, 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. Please ship additional NovoEight material, as specified below, to complete the in-support testing.

--(b)(4)---	250 IU/vial	two (2) vials
--(b)(4)---	250 IU/vial	five (5) vials
--(b)(4)---	1000 IU/vial	two (2) vials
--(b)(4)---	2000 IU/vial	three (3) vials
--(b)(4)---	3000 IU/vial	three (3) vials

Please ship the material to the address below:

Karen Campbell
Regulatory Coordinator
Division of Biological Standards and Quality Control (DBSQC)
OCBQ/CBER/FDA HFM-680
NLRC, Bldg. B, Rm. 2410
5516 Nicholson Lane, Kensington, MD 20895
Office (301)594-6255

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 May 10, 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

Telephone: 301-827-6116

Fax: 301- 827-2857

Leigh.Pracht@fda.hhs.gov

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Page Last Updated: 11/15/2013

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