

Information Request Email, December 7, 2012 - Novoeight

From: Pracht, Leigh
Sent: Friday, December 07, 2012 12:59 PM
To: 'CDCA (Cindy Cao)'
Subject: STN 125466/0 Information Request
Our Reference: BL 125466/0
Novo Nordisk Inc.
Attention: Cindy Cao, PhD
December 7, 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. Please provide financial certification and disclosure information (form 3454) for all investigators who participated in Study NN7008-3522 and NN7008-3600.
2. Please submit the information on pediatric studies as required by Pediatric Research Equity Act.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

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

Please submit your responses to this information request by January 7, 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.

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

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other

action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

Page Last Updated: 11/15/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [ةيبرعلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [ىسراف](#) | [English](#)