

Information Request Email, December 17, 2012 - Novoeight

From: Pracht, Leigh
To: CDCA (Cindy Cao)
Subject: RE: STN 125466/0 Information Request
Date: Monday, December 17, 2012 10:49:00 AM
Dr. Cao,

We acknowledge your intent to submit the requested financial certification and disclosure information, and agree with your proposal to submit a pediatric assessment under section

1.9.5, Proposal for Written Agreement of Module 1.9, Pediatric Administrative Information. Section 505b(a)(2) of the Pediatric Research Equity Act states: Under PREA, the pediatric assessment should contain data gathered from pediatric studies using appropriate formulations for each age group for which the assessment is required, and other data that are adequate to:

- Assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations
- Support dosing and administration for each pediatric subpopulation for which the drug or the biological product has been assessed to be safe and effective

For each of the following age groups please provide an assessment of the data gathered to support the safety and efficacy of this product in the pediatric population:

- a. 0 to <2 years,
- b. ≥ 2 years to <6 years,
- c. ≥ 6 years to <12 years,
- d. ≥ 12 years to <16 years of age)

Best regards,

Leigh A. Pracht Regulatory Project Manager FDA/CBER/OBRR/DBA WOC1; RM562N; HFM-380

1401 Rockville Pike

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Telephone: 301-827-6116

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From: CDCA (Cindy Cao) [mailto:cdca@novonordisk.com]

Sent: Tuesday, December 11, 2012 1:41 PM

To: Pracht, Leigh

Subject: RE: STN 125466/0 Information Request

Dear Leigh,

I have some further questions/clarifications to your request below.

1) For the financial certification and disclosure information (form 3454) for all investigators who participated in Study NN7008-3522 and NN7008-3600, we initially did not send in because the "covered studies" as defined per 21 CFR 54.2(e) as "This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), ---". NN7008-3600 was a local Japanese PK trial and NN7008-3522 was conducted in non-US countries prior to the opening of IND14059. Therefore we decided that these two studies are not "covered studies". As the Agency now requests for this, we will be happy to provide this information.

2) Regarding pediatric studies, in the BLA, we have submitted the synopsis and the full CTR for the pediatric PTP study NN7008-3545 in Module 5.3.5.2., and for the pediatric PUP study NN7008-3809, the full study protocol is embedded in Module 1.16 as an Appendix for the Risk Management Plans. The pediatric PUP study NN7008-3809 protocol has also initially been submitted to the Agency under IND 14059 on Aug 26, 2011 (Serial #0032), and amended on March 22, 2012 (Serial # 0043) and Sept. 14, 2012 (Serial # 0065). Therefore, we feel that sufficient information has been submitted to the Division.

We take this request as only to provide a Pediatric Study Assessment in Module 1.9 Pediatric administrative information. Specifically in Module 1.9.5. Proposal for written agreement. Do you agree and can you please ask the reviewer to clarify and provide more details on this request?

Thanks you in advance for the answers/clarifications to the above. Best,

Cindy

Cindy Cao Ph.D Senior Manager Regulatory Affairs

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From: Pracht, Leigh [mailto:Leigh.Pracht@fda.hhs.gov]
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: Please provide financial certification and disclosure information (form 3454) for all investigators who participated in Study NN7008-3522 and NN7008-3600.

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

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Page Last Updated: 11/15/2013

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