

# Record of Midcycle Telephone Communication, April 17, 2013 - Novoeight

**Application type and number:** Original BLA STN 125466/0  
**Product name:** Antihemophilic Factor (Recombinant), Plasma/Albumin Free [NovoEight]  
**Applicant:** Novo Nordisk Inc.  
**Meeting date & time:** Wednesday, April 17<sup>th</sup>, 2013, 10:00 – 11 a.m.  
**Telecon Numbers** -----(b)(4)----- (Technical Problems), -----(b)(4)-----  
-  
**Committee Chair:** Natalya Ananyeva, Ph.D., OBRR/DH/LH  
**RPM:** Leigh Pracht, CSO, OBRR/DBA/RPMB

## **FDA Attendees:**

Natalya Ananyeva, PhD, OBRR/DH/LH  
Christopher Joneckis, PhD, OD/RMS  
Leigh Pracht, OBRR/DBA/RPMB  
Kimberly Taylor, CDER/OPI/OPA/PES  
Patrick Zhou, Independent Assessor, Eastern Research Group

## **Novo Nordisk Attendees:**

Frank Bringstrup – Senior Regulatory Project Manager  
Knud Vad – Project Vice President  
Jens-Peder Pedersen – Project Vice President  
Henrik Kim Nielsen – Corporate Vice President, Regulatory Affairs  
Anders Lindblom – International Medical Director  
Karin Knobe – Vice President, Medical & Science  
Stephanie Seremetis – Chief Medical Officer - hemophilia  
Hanne Kjær Offenbergsen – Senior Non-clinical Project manager  
Niels Kristian Klausen – Senior CMC Project Manager  
Anja Suddergaard – Safety Surveillance Adviser  
Lewis Pollack – Senior Director, Regulatory Affairs  
Judi Møss – Senior Clinical Pharmacology Advisor  
Anders Rosholm – Statistics Specialist  
Anne Prener – Senior Vice President for Hemophilia  
Sanne Slot Valentin – Vice President, CMC  
Bob Clark – Vice President, Regulatory Affairs  
Trine Saugstrup, Statistician  
Robert Gut, Vice President, Clinical Development and Medical Affairs  
Rafeya Khan – Senior Associate, Regulatory Affairs  
Thomas Ørts Pedersen, Project Vice President, Device R&D  
Erik Halkjær – Principal Scientist, CMC  
Tim Tue Wodskou, Senior Regulatory Professional

Dorte Bjorn-Larsen – Regulatory Specialist  
Anja R. H. Skands – Senior Drug Product Coordinator  
Andrew Chang – Executive Director, Regulatory Affairs

### **Discussion Summary:**

1. No significant issues with the data submitted in the BLA have been identified by the review committee to date.
2. An Information Request was sent to the Applicant on April 9<sup>th</sup>, 2013 with the due date for the responses on May 13<sup>th</sup>, 2013.
3. Regarding responses to inspectional FDA Form 483 items, Novo Nordisk should submit the resolution plan with the tentative completion dates for each item by May 1<sup>st</sup>, 2013.
4. Clarification on FDA request to validate the clearance of an additional enveloped virus by the manufacturing process for turoctocog alfa Drug Substance and anti-FVIII monoclonal antibody: Novo Nordisk may proceed with clearance studies using -----(b)(4)----- as proposed in their memorandum dated April 10<sup>th</sup>, 2013.
5. As discussed during the Pre-License Inspection, please submit the list of raw materials/ ingredients used in the manufacture of turoctocog alfa drug substance/drug product in order of decreasing risk as assessed by Novo Nordisk, and provide information on the suppliers/manufacturers of risk materials. No due date has been specified; please submit as an amendment to the file at the earliest possible date. Any further clarification required pertaining to the list of raw materials will be discussed via email.
6. The review of the clinical data to date did not raise major safety concerns. In item 13 of the April 9<sup>th</sup> Information Request, FDA requested formatting the datasets to enable verification of the trial results (the inhibitor rate, annualized bleeding rate and demographic data). As agreed upon during the April 15<sup>th</sup> teleconference, Novo Nordisk will submit the data in the appropriate format as an amendment to the file by COB April 22<sup>nd</sup>. If the data are available earlier, Novo Nordisk will send them by e-mail.
7. The review committee (currently) does not think that a Risk Evaluation and Mitigation Strategy (REMS) is required.
8. This BLA will not be presented at Blood Products Advisory Committee meeting.
9. As agreed upon between FDA and Novo Nordisk during the Pre-License Inspection, Novo Nordisk will submit the complete stability report for turoctocog alfa

Drug Substance, Drug Product and Diluent as a response to the April 9<sup>th</sup> Information Request (items 4 and 5) by May 13<sup>th</sup>, 2013. This will also fulfill Novo Nordisk's commitment for updated stability data stated in FDA Meeting Response Memorandum dated June 8<sup>th</sup>, 2012 (IND 14059; CRMTS #8473, questions 2, 5, and 8).

10. The late-cycle meeting has been scheduled for Friday, June 28, 2013 1:30 - 3 p.m. Over the course of the next two months, it will be decided as to whether the late cycle meeting will be a telecon or a face to face meeting.

END

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