

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 17th, 2013, 10:00 – 11 a.m.
Telecon Numbers -----(b)(4)----- (Technical Problems), -----(b)(4)-----
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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 9th, 2013 with the due date for the responses on May 13th, 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 1st, 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 10th, 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 9th 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 15th teleconference, Novo Nordisk will submit the data in the appropriate format as an amendment to the file by COB April 22nd. 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 9th Information Request (items 4 and 5) by May 13th, 2013. This will also fulfill Novo Nordisk's commitment for updated stability data stated in FDA Meeting Response Memorandum dated June 8th, 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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