

# Labeling Letter - Novoeight

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Service

Public Health

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Food and  
Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Our Reference: BL125466/0

Novo Nordisk Inc.

Attention: Lewis Pollack, PhD

September 9, 2013

Sent by email

Dear Dr. Pollack:

We are reviewing your October 15, 2012 biologics license application (BLA) for Antihemophilic Factor (Recombinant) [Novoeight]. We determined that the following information is necessary to continue our review:

1. We have reviewed the package insert submitted on August 23, 2013, and request changes be made in accordance with the attached MS Word document.
2. You may use the proprietary name with the initial letter capitalized (Novoeight) in the print package insert. However, please note that the name will appear as NOVOEIGHT in SPL (DailyMed, etc.).
3. Please delete “Plasma/Albumin Free” from the proper name and adjust the proprietary name in the carton and vial labels, and re-submit the mock-up.
4. Please note that the actual FVIII activity values (determined by the one-stage clotting and the chromogenic substrate assays) should be stated on carton and vial for product distribution (please refer to September 9th, 2013 CMC Information Request for further details).
5. Please use definitions “reconstitution”, “reconstituted” in sections 2.2 and 2.3 (definitions “mixing”, “mixed” were deleted).
6. You may request a teleconference if any clarifications are needed.

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 September 12, 2013 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. 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 16, 2013.

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh Pracht  
Regulatory Project Manager  
FDA/CBER/OBRR/DBA/RPMB

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