

Proprietary Name Review Letter, November 16 2012 - Novoeight

DEPARTMENT OF HEALTH & HUMAN SERVICES
Service

Public Health

Food and
Drug Administration

1401 Rockville Pike

Rockville, MD 20852-1448

Our Reference: STN 125466/0

Novo Nordisk, Inc.
Attention: Robert B. Clark
P.O. Box 846
Plainsboro, NJ 08536

Dear Mr. Clark:

We have reviewed your submission dated October 16, 2012 to your biologics license application (BLA) for Antihemophilic Factor (Recombinant), Plasma/Albumin Free, requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, NovoEight, is acceptable at this time.

We will perform another proprietary name review of NovoEight closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

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

Sincerely yours,

/s/

Basil Golding, M.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Page Last Updated: 11/15/2013

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