

Concurrence Memo - Novoeight

Memorandum
Health and Human Services

Department of

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Research

Date:

To: Administrative file, STN 125466/0, Antihemophilic Factor (Recombinant) Plasma/Albumin Free (turoctocog alfa)
From: John A. Eltermann, Jr., R.Ph., M.S., Director, DMPQ/OCBQ/CBER
Through: Mary A. Malarkey, Director, OCBQ/CBER
Subject: Concurrence with the primary and addendum reviews

SUMMARY

This Biologics License Application was submitted by Novo Nordisk and reviewed as a standard 12 month review under PDUFA V. The primary DMPQ review of this file for CMC and facility information was conducted by Dr. Randa Melham of Manufacturing Review Branch 2. The final product is a lyophilized and is reconstituted with sterile 0.9 % NaCl diluent. There are 6 strengths of the product ranging from 250 IU to 3000 IU.

There are several manufacturing facilities for this product. The drug substance is manufactured at the Novo Nordisk facility in ---(b)(4)---, Denmark. The drug product is formulated, filled and lyophilized at the Novo Nordisk ---(b)(4)---, Denmark facility. The diluent is manufactured by a contract manufacturer, -----(b)(4)-----.

Since the drug substance facility was new, a pre-license inspection of the drug substance manufacturing facility was conducted at the Novo Nordisk A/S facility in ---(b)(4)---, Denmark from -----(b)(4)-----.

I have reviewed the primary review memo, addendum memo, and find the issues have been adequately addressed and concur with the reviewer's recommendation to approve this BLA.

<https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/default.htm>

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