

**From:** [Dehdashti, Seameen \(Jean\)](#)  
**To:** ["BDV \(Barbara Davies\)"](#)  
**Cc:** [Dehdashti, Seameen \(Jean\)](#)  
**Subject:** FDA Information Request (IR) RE: BLA 125671/0  
**Date:** Tuesday, April 03, 2018 9:01:25 PM  
**Attachments:** [image002.png](#)  
**Importance:** High

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Good afternoon Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. The FDA review team is requesting the information outlined below in **bold text**. We request that these samples, reagents and documentation be sent by close of business (COB), Friday, April 27, 2018, or notify CBER by this date when the shipment can be expected.

**FDA Information Request: Sample and Reagent IR for 125671/0 Antihemophilic Factor (Recombinant), GlycoPEGylated**

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**1. Please provide (b) (4) vials per lot of Antihemophilic Factor (Recombinant), GlycoPEGylated.**

**CBER requests the following lots:**

- a. (b) (4) (500 IU/v)
- b. (b) (4) (500 IU/v)
- c. (b) (4) (1000 IU/v)
- d. (b) (4) (3000 IU/v)

**2. Please provide reagents/documentation for the following test methods:**

a. (b) (4) and Protein content

- Turoctocog alfa pegol material for (b) (4), sufficient for 3 runs (preferably in separate vials)
- Turoctocog alfa pegol control (with established limits of (b) (4))
- Turoctocog alfa pegol reference material with COA sufficient for 3 runs (preferably in separate vials)
- Please provide historical information of any (b) (4) that failed the (b) (4) procedure

b. Potency (chromogenic assay (b) (4))

- DP in-house standard, (b) (4) vials
- DP in-house control, (b) (4) vials
- Please provide information about the assigned values and volumes of reconstitution for the standard and control, unless they are stated in the SOP for test method.

- Please submit the SOP for test method  
(b) (4)

**3. Please provide the most recent test results for the requested lots for the assays listed below.**

**Include the date of the test for each of the lots.**

a. (b) (4)

b. Protein content

c. Potency

**The samples and reagents should be shipped to:**

**Al Del Grosso**

**Food and Drug Administration**

**Center for Biological Evaluation and Research**

**Division of Biological Standards and Quality Control**

**10903 New Hampshire Avenue**

**WO75, G-717**

**Silver Spring, MD 20993-0002**

**Contact Al Del Grosso at 240-402-9470 ([alfred.del-grosso@fda.hhs.gov](mailto:alfred.del-grosso@fda.hhs.gov)) or Marie Anderson at 240-402-6292 ([marie.anderson@fda.hhs.gov](mailto:marie.anderson@fda.hhs.gov)) for questions on the shipment.**

Please confirm receipt of my e-mail, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

**Jean Dehdashti, MSc, RAC**

***Regulatory Project Manager***

**Center for Biologics and Evaluation**

**Office of Tissues and Advanced Therapies**

**U.S. Food and Drug Administration**

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