

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

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

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) or Marie Anderson at 240-402-6292 (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

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