

**From:** [Dehdashti, Seameen \(Jean\)](#)  
**To:** ["BDV \(Barbara Davies\)"](#)  
**Cc:** [Dehdashti, Seameen \(Jean\)](#)  
**Subject:** FDA Information Request (IR): BLA 125671/0  
**Date:** Friday, June 01, 2018 8:31:00 AM  
**Attachments:** [image002.png](#)  
**Importance:** High

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Dear Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. We are reviewing your BLA submission for Antihemophilic factor, GlycoPEGylated (STN125671) and have the following information request (IR), outlined in **bold text** below. Please respond within 8 Weeks of receiving this IR, by Friday, July 27, 2018.

**FDA Information Request:**

1) **(b) (4)** of the drug substance; however, no detailed description of the assay procedures was provided in the BLA. Please provide the SOP or a detailed description of the test.

2) For the validation of **(b) (4)**

i) **(b) (4)**

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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