

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR)-Pharmacology/Toxicology: BLA 125671/0
Date: Monday, August 06, 2018 9:09:17 AM
Attachments: [image003.png](#)
Importance: High

Good morning 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 provide your response by Friday, August 10, 2018.

FDA Pharmacology/Toxicology IR:

1. **Regarding Study Report #213109:**
 - a. **Please provide SOP A-20018A.2 (dated 10 April, 2018) and QUAL-B20018 (dated 18 May, 2018).**
 - b. **On page 24 of your report, you provide acceptance criteria for your internal standard, please provide this information and chromatograms for the reference standard, (b) (4) , used in your analysis.**
2. **In your response to Question 1b in the FDA Information Request dated July 19th, 2018, you state "Bioanalysis of plasma is on-going and the report for plasma is expected in August 2018. The plasma report can be provided on the Agency's request." Please submit this report as an amendment to this BLA as soon as it is available.**

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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