

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["hpaw@novonordisk.com"](mailto:hpaw@novonordisk.com)
Cc: ["BDV \(Barbara Davies\)"; Dehdashti, Seameen \(Jean\)](#)
Subject: FW: FDA Pharmacology/Toxicology Information Request (IR): BLA 125671/0
Date: Thursday, July 19, 2018 12:35:02 PM
Attachments: [image001.png](#)
[image007.png](#)
Importance: High

Dear Hiral,

I received an out-of-office notification from Barbara Davies that provided your contact information.

Please see FDA issued Pharmacology/Toxicology IR below for BLA 125671/0, with a response request date of Tuesday, July 24, 2018.

Please confirm receipt of this communication, 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
Tel: 240-402-9146
Seameen.Dehdashti@fda.hhs.gov



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From: Dehdashti, Seameen (Jean)
Sent: Thursday, July 19, 2018 12:23 PM
To: 'BDV (Barbara Davies)' <bdv@novonordisk.com>
Subject: FDA Pharmacology/Toxicology Information Request (IR): BLA 125671/0
Importance: High

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 provide your response by Tuesday, July 24, 2018.

FDA Pharmacology/Toxicology IR:

1. In Study Report #301333 you have used (b) (4) to evaluate the presence of PEG in cerebrospinal fluid (CSF) and plasma samples from your 52-week toxicity study in the rat. Additionally, on page 8 of Study Report #301507 you state: “Novo Nordisk A/S is currently examining if a more sensitive method can be identified (e.g., (b) (4) or (b) (4) for future analysis”.

- a. Please provide a justification for the use of (b) (4) over other, potentially more sensitive, assays.
- b. Please clarify whether samples from Study #213109 will be retested using a different method as suggested above.

2. Please clarify whether the linker remains attached to the PEG after rFVIII activation.

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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