

From: [Dehdashti, Seameen \(Jean\)](#)
To: "BDV (Barbara Davies)"
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR): BLA 125671/0
Date: Thursday, May 24, 2018 11:58:53 AM
Attachments: [image002.png](#)
Importance: High

Dear 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**. Please provide your response by close of business (COB), Tuesday, May 29, 2018, and please notify me, if you are not able meet the proposed due date.

FDA Information Request:

We refer to your Human Factors Validation Study Results Report for BLA 125671 submission for Recombinant, glycopegylated human coagulation factor VIII submitted on February 27, 2018. We note in your Human Factors Validation study you did not include an arm of untrained patients/caregivers. Please provide rationale for the absence of an untrained patient and caregiver user group within the study participants for the Human Factors Study Protocol.

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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