

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR)-Clinical: BLA 125671/0
Date: Tuesday, July 31, 2018 1:24:46 PM
Attachments: [image002.png](#)
Importance: High

Good afternoon 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 03, 2018.

FDA Clinical IR:

To facilitate our clinical review, please submit, in a tabular format, the following summary information on the 55 subjects who were randomized in Study 3859 Ext1 to receive treatment either Q3-4 D or Q 7D:

Table 1:

1. **Subject ID**
2. **Subject's genotype**
3. **Treatment regimen (i.e., prophylaxis or on-demand) prior to enrolling in the trial**
4. **Number of bleeds during the 12 months prior to enrolling in the trial.**
5. **Number of bleeds during the main phase of the study**
6. **Number of bleeds during Ext 1**
7. **Regimen that the subject remained on or switched to at the end of Ext1 (Q3-4 D vs. Q 7D)**
8. **Disposition**

Please include more details in as separate table, to include the following information:

Table 2:

1. **Subject ID**
2. **Details on each bleeding event that occurred during the main study and during Ext 1 to include:**
 - a. **Bleed type (spontaneous or traumatic)**
 - b. **Study Day of bleeding event**
 - c. **Intervention (factor infusion or other treatment)**
 - d. **If factor is used, number of injections needed to treat each bleed.**

Please submit the above information in a word document if possible.

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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