

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR)-Biostatistics: BLA 125671/0
Date: Friday, July 13, 2018 8:27:01 AM
Attachments: [image002.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, July 20, 2018.

FDA IR (Biostatistics):

- 1. In modules 2.7.3 and 2.7.4, please provide the SAS analysis programs and the descriptions used to obtain the outputs in summary of clinical efficacy (Appendix 6.1) and summary of clinical safety reports (Appendix 7.1).**
- 2. Please clarify if the analysis data sets provided for the integrated summary of safety report in module 5.3.5.3 were used to obtain the outputs for the integrated summary of efficacy report. If not, please provide the analysis data sets for the integrated summary of efficacy report in module 5.3.5.3.**

Please confirm receipt of my e-mail, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

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Regulatory Project Manager

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