

**From:** [Dehdashti, Seameen \(Jean\)](#)  
**To:** "BDV (Barbara Davies)"  
**Cc:** [Dehdashti, Seameen \(Jean\)](#)  
**Subject:** FDA Information Request (IR): BLA 125671/0  
**Date:** Wednesday, May 23, 2018 11:02:28 AM  
**Attachments:** [image002.png](#)  
**Importance:** High

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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), Thursday, June 7, 2018, and please notify me, if you are not able meet the proposed due date.

**FDA Information Request:**

**We have the following information request regarding the analytical procedure (b) (4) "Protein Content and (b) (4)**

- 1. In your analytical procedure, you indicated the number of injection as "A suitable number." This is too vague to describe the number of injections needed to meet system suitability acceptance criteria for the control. Please specify the number of injections.**
- 2. At the (b) (4) step, it is impossible to evaluate the protein content (one of the three SST acceptance criteria for the control) because the calibration curve is not run yet. Please provide appropriate system suitability criteria (e.g., in terms of (b) (4) consistency) for the procedure.**

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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