

**From:** [Dehdashti, Seameen \(Jean\)](#)  
**To:** "BDV (Barbara Davies)"  
**Cc:** [SHSK \(Shawn Hoskin\)](#); [Dehdashti, Seameen \(Jean\)](#)  
**Subject:** FDA Information Request (IR) RE: BLA 125671/0  
**Date:** Tuesday, March 13, 2018 12:51:04 PM  
**Attachments:** [image001.png](#)  
**Importance:** High

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Good afternoon Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. The FDA/CBER CDISC validation team has identified the issues outlined below in **bold text**. Please provide a response no later than close-of-business (COB), Thursday, March 15, 2018. Please let me know if you are not able to meet this deadline.

**FDA Information Request (CBER CDISC):**

- 1. The 3776 and 3885 extension studies are missing the AE, CE and CM domains, even though the SUPPAE, SUPPCE and SUPPCM domains have been provided. The reviewer's guides do not explain why these domains are missing. The reviewer's guides and define.xml document the AE, CE and CM domains, explain validation rules, etc. Please clarify, and provide the missing AE, CE and CM domains accordingly.**
- 2. The data given in the 4033 SDTM package is IDENTICAL to the 3776 SDTM package. Looking at the trial design, exposure domain, etc., it is very clear that the 3776 SDTM data was copied into the 4033 folder. The data was programmatically checked, and all records, in all SDTM domains, are identical between the 3776 and 4033 studies except there are AE, CE and CM domains in 4033 SDTM package (but in data study name is 3776). Please clarify why the data given in the 4033 SDTM package is identical to the 3776 SDTM package.**

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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