

**From:** [Dehdashti, Seameen \(Jean\)](#)  
**To:** ["BDV \(Barbara Davies\)"](#)  
**Subject:** RE: FDA Information Request (IR) RE: BLA 125671/0  
**Date:** Friday, March 16, 2018 11:05:11 AM  
**Attachments:** [image002.png](#)  
[image013.png](#)

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Dear Barbara,

In addition to the FDA CDISC IR items #1 - #6, issued on Thursday, March 15, 2018, FDA CDISC and review team have identified IR #7, listed below in **bold text**. Please provide a response to FDA CDISC IR items #1 - #7 by COB, Thursday, March 22, 2018.

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

- 7. In Study 4033 (and possibly study 3776) AE SDTM dataset, 22 (50%) records appear to be duplicate records, even though they seem to be different events in the ADAM datasets. Please correct the duplications in the SDTM datasets.**

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***

Center for Biologics and Evaluation  
Office of Tissues and Advanced Therapies  
U.S. Food and Drug Administration  
Tel: 240-402-9146  
[Seameen.Dehdashti@fda.hhs.gov](mailto:Seameen.Dehdashti@fda.hhs.gov)



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**From:** BDV (Barbara Davies) [mailto:bdv@novonordisk.com]  
**Sent:** Thursday, March 15, 2018 8:46 AM  
**To:** Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>  
**Subject:** RE: FDA Information Request (IR) RE: BLA 125671/0

Good morning Jean,

I acknowledge receipt of this IR, and will let you know as soon as possible if we are not able to meet the target response date.

I note that NNI responded to the IR dated March 13 on March 14. Let me know if you do not see this submission (SN 0002, STN 125671).

Best regards,  
Barbara

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**From:** Dehdashti, Seameen (Jean) [<mailto:Seameen.Dehdashti@fda.hhs.gov>]  
**Sent:** Thursday, March 15, 2018 8:40 AM  
**To:** BDV (Barbara Davies)  
**Cc:** Dehdashti, Seameen (Jean)  
**Subject:** FDA Information Request (IR) RE: BLA 125671/0  
**Importance:** High

Good morning Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. The FDA/CBER CDISC validation team has identified additional issues outlined below in **bold text**. Please provide a response no later than close-of-business (COB), Thursday, March 20, 2018. Please let me know if you are not able to meet this deadline.

**FDA Information Request (CBER CDISC): We have identified several issues with the BLA datasets you have provided and are seeking some clarifications and or corrections.**

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1. **SDTM ~ ADaM Traceability:** there are 21 subjects in the 3859 extension 2 Study where their ARM values in the SDTM demographics domain (DM) do not match the ARM values in ADSL. Please correct the discrepancy.
2. **File names:** most supporting documents (e.g. reviewer's guides, protocols, etc.) hyperlinked within the define.xml files have the incorrect filename listed in the hyperlink. All the documents appear to be present, however, they can only be opened manually rather than using the hyperlinks in the define.xml). Please correct the documents so that the hyperlinks are functional.
3. **In some studies, comments are provided in SUPPQUAL instead of Comments (CO) domains. Please provide all comments in the CO domains.**
4. **In some studies, high percentage of screen failure subjects do not have information in IE domain. Please make necessary corrections.**
5. **In study 3885, 126 (3.6%) events are missing start date/time. Please insert the missing information.**
6. **In some studies, high percentage of subjects are missing Date/time of Informed Consent (RFICDTC). Please submit the missing data.**

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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