

From: [Dehdashti, Seameen \(Jean\)](#)
To: "BDV (Barbara Davies)"
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR) RE: BLA 125671/0
Date: Thursday, March 22, 2018 3:57:39 PM
Attachments: [image002.png](#)
Importance: High

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 additional issues outlined below in **bold text**. Please provide a response no later than close-of-business (COB), Wednesday, March 28, 2018. Please let me know if you are not able to meet this deadline.

FDA Information Request:

Please send us a list of all clinical study sites in a tabular format to include the following information for each site:

- **Site ID or number**
- **Site name and country**
- **Principal investigator**
- **Total number of subjects treated at each site (please indicate the study protocols IDs under which subjects were treated)**
- **Number and List of serious adverse events**
- **Protocol deviations**

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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