

From: [Dehdashti, Seameen \(Jean\)](#)
To: "BDV (Barbara Davies)"
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR): BLA 125671/0
Date: Thursday, May 17, 2018 1:16:19 PM
Attachments: [image002.png](#)

Good afternoon 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, May 24, 2018, and please notify me, if you are not able meet the proposed due date.

FDA Information Request:

For each of the Non-U.S. clinical investigators who conducted protocol NN7088-3859, please furnish a list of 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**
- **Confirmation (Yes or No) of whether the investigator conducted protocol NN7088-3859 under the corresponding Investigational New Drug application (IND) for the study product. If such information was already submitted, please direct us to the section in the BLA where this information is found."**

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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