

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR): BLA 125671/0
Date: Friday, July 06, 2018 8:53:52 AM
Attachments: [image002.png](#)
Importance: High

Dear Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. We are reviewing your BLA submission for Antihemophilic factor, GlycoPEGylated (STN125671) and have the following information request (IR), outlined in **bold text** below. Please provide your response by Friday, July 20, 2018.

FDA Information Request:

In Section, 3.2.5. of the submission, a (b) (4) method was used to determine the particulate matter of the drug product; however, no detailed description of the assay procedures was provided in the BLA. Please provide the SOP or a detailed description of the test by July 20, 2018.

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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