

From: [Dehdashti, Seameen \(Jean\)](#)
To: "BDV (Barbara Davies)"
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR) : BLA 125671/0
Date: Wednesday, May 02, 2018 6:23:56 PM
Attachments: [image002.png](#)
Importance: High

Good evening 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), Friday, May 18, 2018, and please notify me, if you are not able meet the proposed due date.

FDA Information Request:

Please provide an explanation of your rationale for the selection of the chromogenic substrate (CS) assay over the one-stage clotting (OC) assay for the assignment of Factor VIII potency value of your product. Please also provide a table comparing the Factor VIII potency value derived from the CS assay to that from the OC assay for all final drug product lots manufactured to date, with the respective CS/OC ratio.

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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