

**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***

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)



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.