

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Wednesday, September 12, 2018 2:26 PM
To: BDV (Barbara Davies)
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request (IR)-Pharmacology/Toxicology: BLA 125671/0

Good afternoon 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, September 14, 2018, and let me know if you are not able to meet the requested due date.

FDA Pharmacology/Toxicology IR:

In study #216366 you reference samples collected from rats that were administered 40 kDa PEG in Study # 212213 which does not appear to have been submitted under this BLA. Please submit Study #212213 as an amendment under this BLA.

Please 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

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