

Dehdashti, Seameen (Jean)

From: BDV (Barbara Davies) <bdv@novonordisk.com>
Sent: Friday, September 14, 2018 8:07 AM
To: Dehdashti, Seameen (Jean)
Subject: RE: FDA Information Request (IR)-Pharmacology/Toxicology: BLA 125671/0

Dear Jean,

My group in HQ says that the two reports from requests 1 and 2 can be submitted separately on Monday 17 Sept, or together with the response to request 3 on Thursday 20 Sept. Please confirm the reviewer's preference.

Thank you,
Barbara

From: Dehdashti, Seameen (Jean) [mailto:Seameen.Dehdashti@fda.hhs.gov]
Sent: Thursday, September 13, 2018 1:30 PM
To: BDV (Barbara Davies)
Subject: RE: FDA Information Request (IR)-Pharmacology/Toxicology: BLA 125671/0

Dear Barbara,

FDA Pharm/Tox review team have identified additional missing information, outlined below in **bold text**. I have combined the Pharm/Tox IR, issued September 12, 2018, with the Pharm/Tox IR issued today, September 13, 2018. We would appreciate a response by close of business Friday, September 14, 2018. My apologies for the short notice, please do let me know if you are not able to meet the proposed response date.

FDA Pharmacology/Toxicology IR:

1. 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.
2. In study #213392 you reference data from study #212115 which was not submitted under this BLA. Please submit study #212115 as an amendment to this BLA.
3. Please provide a discussion regarding the discrepancy in the amount and duration of PEG detected in the choroid plexus via (b) (4) in studies #212398, 213038, 216366.

Please confirm receipt of this communication, 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



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.

From: BDV (Barbara Davies) <bdv@novonordisk.com>
Sent: Wednesday, September 12, 2018 3:03 PM
To: Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>
Subject: RE: FDA Information Request (IR)-Pharmacology/Toxicology: BLA 125671/0

Good afternoon Jean,

I have sent this request to the team in Denmark, but do not expect to hear from them until tomorrow. Until I communicate with them, I cannot confirm we are able to meet the time frame.

Warm regards,
Barbara

From: Dehdashti, Seameen (Jean) [<mailto:Seameen.Dehdashti@fda.hhs.gov>]
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
Tel: 240-402-9146
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.