

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Monday, December 17, 2018 2:45 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: RE: FDA Information Request - Statistical/Clinical: BLA 125671/0
Attachments: BLA125671_0_UpdatedTables.pdf

Dear Barbara,

As a follow-up to our teleconference earlier today, and FDA statistical/clinical information requests (IRs) issued December 13 and December 16, 2018, attached please find a list of updated tables requested by FDA review team. In addition, throughout the updated results, please provide the ABRs based on the observed data without any imputations, if not already done so in the original submission.

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



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From: BDV (Barbara Davies) <bdv@novonordisk.com>
Sent: Monday, December 17, 2018 8:50 AM
To: Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>
Subject: RE: FDA Information Request - Statistical/Clinical: BLA 125671/0

Dear Jean,

After considering this IR and looking at our timelines, we respectfully request a teleconference with FDA as soon as possible. We can make a small group of Novo Nordisk participants available later today, tomorrow or Wed morning.

Our discussion points are:

- The analyses requested were not a topic at the LCM; i.e., the outcome assessments seem to have changed in the recent past
- We will provide everything the FDA requests, but are not able to provide everything within the specified target response dates
- We need clarification on the tables/assessment of hemostatic response, as this endpoint is calculated based on the time of product administration; thus there is no hemostatic response data for non-treated bleeds

Again, we request a teleconference at the earliest possible time.

Best regards,
Barbara

Barbara Davies
Senior Manager
Regulatory Affairs, CMR

Novo Nordisk Inc.
1-609-786-4774
1-609-651-9687 (mobile)
bdv@novonordisk.com

From: Dehdashti, Seameen (Jean) [<mailto:Seameen.Dehdashti@fda.hhs.gov>]
Sent: Sunday, December 16, 2018 2:03 PM
To: BDV (Barbara Davies)
Cc: Dehdashti, Seameen (Jean)
Subject: RE: FDA Information Request - Statistical/Clinical: BLA 125671/0

Dear Barbara,

Please see the new statistical/clinical IR issued below by the review team, where Novo Nordisk response to part (1) of the IR will need to be included in your December 20, 2018, response to the IR issued on December 13, 2018. Please provide a response to part (2) of the IR by close of business Thursday, January 3, 2019.

FDA Information Request – Statistical/Clinical:

- 1. Please provide the analysis datasets and the programs, together with the updated results as requested in the IR issued on December 13, 2018, no later than December 20, 2018.**
- 2. Please provide updated results including the non-treatment required bleeds together with the analysis datasets and the programs for the following tables, if not already included in the IR request dated December 13, 2018, no later than January 3, 2019:**

**Trial 3859 main part report: Tables 11-1---11-6,
Tables 14.2.86---14.2.91, 14.2.17---14.2.25, 14.2.93, 14.2.94**
**Trial 3859 extension part 2: Tables 11-1---11-4, 11-7, 11-9,
Tables 14.2.25---14.2.27, 14.2.79, 14.2.80, 14.2.88, 14.2.89**
**Trial 3885 main part report: Tables 11-1---11-5
Tables 14.2.21, 14.2.22, 14.2.34**
Trial 3885 extension part: Tables 11-1---11-5

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

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From: BDV (Barbara Davies) <bdv@novonordisk.com>
Sent: Thursday, December 13, 2018 5:44 PM
To: Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>
Subject: RE: FDA Information Request - Statistical/Clinical: BLA 125671/0

Dear Jean,

Please ask your reviewers if – given the IR below – we still need to respond to the Clinical IR dated Dec 13 and due tomorrow, Dec 14. Alternatively, we would like to respond to both Clinical IRs together at the later date (Dec 20, which I am still trying to confirm with the team).

Thank you,
Barbara

Barbara Davies
Senior Manager
Regulatory Affairs, CMR

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bdv@novonordisk.com

From: Dehdashti, Seameen (Jean) [<mailto:Seameen.Dehdashti@fda.hhs.gov>]
Sent: Thursday, December 13, 2018 3:19 PM

To: BDV (Barbara Davies)
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request - Statistical/Clinical: BLA 125671/0

Dear Barbara,

We are reviewing your BLA submission for Antihemophilic Factor (Recombinant), GlycoPEGylated, turoctocog alfa pegol (STN 125671), and have the following information request (IR), outlined below in **bold text**. Please send us your response by close of business, Thursday, December 20, 2018, if possible.

FDA Information Request (IR) – Statistical/Clinical:

Please provide updated results including the non-treatment required bleeds for the following tables:

Trial 3859 main part report: Table 11-1, 14.2.87-14.2.91

Table 11-2, 14.2.17-14.2.20

Table 14.2.21-14.2.25

Trial 3859 extension part 1 report: Table 11-1, 14.2.216-14.2.219

Tables 14.2.220-14.2.224

Trial 3885 main part report: Table 11-1

Table 11-4, 14.2.21, 14.2.22

Trial 3885 extension part report: Table 11-1

Table 11-5, 14.2.21, 14.2.22

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

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