

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Thursday, November 01, 2018 3:19 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: RE: BLA 12567/0: Sponsor Minutes of 1 Nov 2018 Teleconference
Attachments: Slides for FDA telecon 01.nov.2018 (002).pptx

Follow Up Flag: Follow up
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Dear Barbara,

Thank you for the provided summary of our teleconference today, November 1, 22018. Please see an additional bullet point that was added by Dr. Bhattacharyya and Dr. Dutt below. Please note that we are in agreement with the summary as captured below, and I will move forward with filing this information accordingly under BLA 125671/0.

Summary of FDA-Novo Nordisk Teleconference on November 1, 2018 RE: BLA 125671/0

- **Agency agreed with Novo Nordisk's approach to use an (b) (4) method to demonstrate the accuracy of the chromogenic assay for Potency (please see attached slides).**
- **Agency suggested and Novo Nordisk agreed to use (b) (4) lots of (b) (4) and (b) (4) lots (different than reference standard) of drug product, in addition to the reference standard, in the one-stage and chromogenic assays for the accuracy study.**
- **Novo Nordisk commits to provide the requested data by November 26, 2018, and will submit earlier if possible.**
- **In view of the agreement between FDA and Novo Nordisk as discussed above, FDA agreed to withdraw the third item sent to Novo Nordisk, which is "Please provide clarification on your inability to conduct accuracy study by (b) (4) and measuring the potency by the chromogenic method."**

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: Thursday, November 01, 2018 2:20 PM
To: Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>
Subject: BLA 12567/0: Sponsor Minutes of 1 Nov 2018 Teleconference

Dear Jean,

Here are the agreements we reached during the teleconference, and one update:

- Agency agreed with Novo Nordisk's approach to use an (b) (4) method to demonstrate the accuracy of the chromogenic assay for Potency
- Agency suggested and Novo Nordisk agreed to use (b) (4) lots of (b) (4) and (b) (4) lots (different than reference standard) of drug product, in addition to the reference standard, in the one-stage and chromogenic assays for the accuracy study
- Novo Nordisk commits to provide the requested data by November 26, and will submit earlier if possible

We thank you and Drs. Dutt and Bhattacharyya for the very useful call earlier today.

Best regards,
Barbara

Barbara Davies
Senior Manager
Regulatory Affairs, CMR

Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
+1 609-987-5800

1-609-786-4774
1-609-651-9687 (mobile)
bdv@novonordisk.com
www.novonordisk-us.com



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