

From: Owosela, Olukayode (Kay)  
Sent: Wednesday, October 17, 2018 10:01 AM  
To: 'BDV (Barbara Davies)'  
Cc: Dehdashti, Seameen (Jean)  
Subject: RE: BL 125671.34 | Information Request

Hi Barbara,

I followed up with the requester regarding the response target date. Please provide a response to the IR sent yesterday by October 24, 2018.

Regards,  
Kay

From: BDV (Barbara Davies) <bdv@novonordisk.com>  
Sent: Wednesday, October 17, 2018 8:27 AM  
To: Owosela, Olukayode (Kay) <Olukayode.Owosela@fda.hhs.gov>  
Cc: Dehdashti, Seameen (Jean) <Seameen.Dehdashti@fda.hhs.gov>  
Subject: RE: BL 125671.34 | Information Request

Dear Mr. Owosela,

I am confirming receipt of the email below. I note there is no response target date. I will try to get an estimate from my team as to the time frame for our response.

Thank you for the email confirming Nov 2 as the new response date for the Oct 12 IR.

Regards,  
Barbara

From: Owosela, Olukayode (Kay) [mailto:Olukayode.Owosela@fda.hhs.gov]  
Sent: Tuesday, October 16, 2018 5:06 PM  
To: BDV (Barbara Davies)  
Cc: Dehdashti, Seameen (Jean)  
Subject: BL 125671.34 | Information Request

Hi Barbara,

We have reviewed your response (125671/0.34 received on 10/11/2018) to our IR dated September 20, 2018. We have following information request regarding the data submitted in Table 1 for the accuracy study.

1. Question 1 of the IR has not been addressed. You have provided the % Recovery data of spike added to a drug product placebo sample based on the nominal assigned potency of a secondary standard (b) (4) and measured potency by your "Analytical Procedure (b) (4) Potency by Chromogenic Assay". Please provide comparative data for the spike recovery using both the chromogenic assay and one stage clotting assay. Alternatively, you can use (b) (4)

For new accuracy study, please also submit the system suitability data for your assay as per section 11 of your Analytical Procedure (3.2.S.4.2 Analytical Procedure (b) (4)

2. You indicated that you obtained comparable results for potency by the chromogenic assay and

one-stage clotting assay for your secondary standard (b) (4) . Please provide the potency data of this standard obtained by the one-stage clotting assay and explain how you found the data comparable.

3. You have used 500IU drug product placebo sample for spiking experiment. Please clarify what this placebo sample is.

Please confirm receipt of this email.

Warm Regards,  
Kay

Kay Owosela, MSc. (Mr.)  
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Center for Biologics Evaluation and Research  
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