



TELECONFERENCE SUMMARY

Application number: BLA STN 125742/0
Product name: COVID-19 Vaccine, mRNA (COMIRNATY)
Proposed Indication: Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older
Applicant: BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
Teleconference date & time: August 17, 2021; 9:00 AM - 9:41 AM PM EDT

FDA Participants:

Ekaterina Allen
 Anissa Cheung, Ph.D.
 John Eltermann, R.Ph., M.S.
 Debra Emerson
 Kathleen Jones, Ph.D.
 Christian Lynch
 Ramachandra Naik, Ph.D.
 Lori Peters, M.S.
 Carolyn Renshaw
 Michael Smith, Ph.D.

Applicant Participants:

Paul Rohlfing,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
Adrienne Stafford,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
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Andrew Nelson,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
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Background/Purpose of this call:

The purpose of the teleconference between DMPQ and Pfizer was to discuss items 2b, 2c, 6 and 9c from the FDA form 483 for the Andover site.

Teleconference Summary:

Follow-up response to FDA form 483 item 2b:

CBER expressed concern about two issues associated with (b) (4)

(b) (4) Pfizer explained that when the (b) (4) interface is in (b) (4) mode it is (b) (4) and controlled by (b) (4), but when switch to (b) (4) mode it is not controlled by (b) (4). The (b) (4) ran in the background while in (b) (4) mode. The data integrity issue was extraneous data seen by the (b) (4) system.

Pfizer said in order to avoid this discrepancy they would need to ensure the (b) (4) software is paused when entering (b) (4) mode.

CBER asked if Pfizer would be willing to commit to correcting this before the next inspection. Pfizer committed to investigate this issue and make the required updates based off of the results.

CBER asked if Pfizer could submit updated responses as an amendment to the BLA regarding these follow-up questions. Pfizer said they would do this initially by e-mail and then submit it as an amendment.

Regarding the extraneous data and data integrity, Pfizer said the (b) (4) ran in the background in the (b) (4) mode. Pfizer also stated that an investigation will be initiated to determine if pausing the (b) (4) software will eliminate collection of extraneous data during (b) (4) operations.

Follow-up response to FDA form 483 item 2c:

CBER asked about Pfizer's response and Pfizer explained that the (b) (4) was a target, not a control limit and not a critical parameter process at that time. Pfizer explained this was a retrospective review in (b) (4) of batch records regarding the less than (b) (4) target.

CBER asked if there were any corrective actions implemented? Pfizer stated that this was an early batch with limited experience and since there was (b) (4) Additionally, the (b) (4) is overall controlled by (b) (4). Pfizer

has now moved this from a target to a control limit, and will therefore be investigated in the case of a control limit excursion. There is no impact for this missed target and this not a critical parameter process.

Pfizer noted that this was originally a (b) (4), but now it is (b) (4) an alarm will sound and the (b) (4) shuts off if that happens.

CBER acknowledged the target vs. control limit information provided in the response; however, CBER also clarified a more general concern regarding the lack of Quality oversight during the batch record review process. CBER noted that moving forward Pfizer should consider ways to enhance their continuous process verification monitoring and batch record review process.

Follow-up response to FDA form 483 item 6:

CBER had clarifying questions regarding a couple of discrepancies in Pfizer's disinfecting studies in (b) (4) and room (b) (4).

In study (b) (4) was (b) (4) on the coupons and shown to be effective with a contact time of (b) (4). However, in another study, (b) (4) the coupons were (b) (4) and results showed that (b) (4) was not effective with a contact time of (b) (4) except on (b) (4).

(b) (4) was effective with a (b) (4) contact time. Pfizer explained that they had (b) (4) studies where (b) (4) was (b) (4) on the surface of the coupons and allowed to (b) (4) and another where the coupons were (b) (4) in (b) (4). Pfizer explained that (b) (4) with (b) (4) and allowing it to (b) (4) worked better than (b) (4).

Pfizer said another study (b) (4) was performed for (b) (4) where the (b) (4) was (b) (4) on the coupons and confirmed the effectiveness of (b) (4) with a contact time of (b) (4).

CBER asked what (b) (4) were used in the (b) (4) (b) (4) and Pfizer replied it was (b) (4).

CBER also asked what (b) (4) were used in the (b) (4) study and Pfizer replied (b) (4).

CBER asked how many replicates the study was performed on and Pfizer replied that it was performed in (b) (4) coupons.

CBER noted there was another discrepancy with (b) (4) used at (b) (4) against (b) (4) against floor and wall surfaces. CBER asked if this was the same issue (b) (4) and Pfizer replied yes it was.

CBER noted that there was an issue identified in (b) (4) (b) (4) study with (b) (4) needed a longer contact time and that the evaluation in (b) (4) did not include a (b) (4) (b) (4), and said that Pfizer might want to consider adding one of these in the future depending on the results of EM studies contain (b) (4) (b) (4).

Follow-up response to FDA form 483 item 9:

Pfizer noted that there was a miscommunication during the inspection and room (b) (4), is not a CMC area but ISO (b) (4) room off of (b) (4) (b) (4). CBER asked if the control room is included in the monitoring and Pfizer replied that is not because it is covered by a legacy strategy.

Pfizer said the results of the proposed monitoring study will determine if room (b) (4) or other perimeter rooms will need to be monitored and the frequency and type of sampling that will be needed.

Pfizer said that they will e-mail a response to CBER today and follow-up with an official amendment, likely on Wednesday, August 18, 2021. The response will contain commitments to 1) investigate how to eliminate data integrity errors when switching to (b) (4) mode to not have (b) (4) running in the background or provide a signal to show that it is running and 2) to clarify type of sampling and frequency of testing for item 9c

END