U.S. FOOD & DRUG ADMINISTRATION

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 16, 2021; 4:00 PM - 4:16 PM EDT

FDA Participants:
Maryna Eichelberger, Ph.D.
Mary Malarkey
Ramachandra Naik, Ph.D.
Michael Smith, Ph.D.

Applicant Participants:

Paul Rohlfing,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
Rich Pelt,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
Roger Nosal,	GCMC Regulatory Affairs, Pfizer Inc.
Brian Picard,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
Andrew Nelson,	GCMC Vaccines Regulatory Affairs, Pfizer Inc.
Donna Boyce,	Global Regulatory Affairs Pfizer Inc.
Carmel Devlin,	Global Regulatory Portfolio Lead, Global Regulatory Affairs, Vaccines, Pfizer Inc.
(b) (6),	Research Development & Medical, Pfizer Inc.
Lavinia Lewis,	Research Development & Medical, Pfizer Inc.
Meg Ruesch,	Analytical R&D, Pfizer Inc.
Dave Cirelli,	Analytical R&D, Pfizer Inc.
(b) (6),	Analytical R&D, Pfizer Inc.
(b) (6),	Quality Operations, Pfizer Global Supply, Pfizer Inc.
(b) (6),	Quality Operations, Pfizer Global Supply, Pfizer Inc.
(b) (6),	Technical Services, Pfizer Global Supply, Pfizer Inc.
(b) (6),	Technical Services, Pfizer Global Supply, Pfizer Inc.

Background/Purpose of this call:
CBER sent Pfizer an Information Request (IR) containing three questions regarding measurement of endotoxins using the (b) (4) LAL procedures on August 6, 2021. Pfizer responded in STN 125742/0.48 that was submitted on August 13, 2021, and CBER thought that Pfizer's response to question 3 regarding measurement of total endotoxin was unacceptable and this teleconference was to clarify this issue.

Teleconference Summary:

CBER explained that we need to have the measurement of total endotoxin activity from the (b) (4) product. CBER explained that we expect the value for total endotoxin activity to be below Pfizer's specifications and clarified that this would not be for the lot release protocol (LRP) template product during this BLA review cycle, but we are requesting a commitment to measure this and revise the LRP template in the near future.

Pfizer asked if there was a (b) (4) that worked and CBER replied that (b) (4) did. However, the results from freshly thawed material wasn't exactly the same as material that was held overnight in the refrigerator. Pfizer was somewhat reluctant to send CBER two different sets of results in Lot Release Protocols and asked if CBER would accept results from the (b) (4) sample only. However, they are committed to providing both sets of results when the assay has been established and verified at all testing sites.

Pfizer will e-mail a revised response to DBSQC's 3rd question from August 6, 2021 IR to review and Pfizer commits to testing the endotoxin from the (b) (4) product. Once the commitment is acceptable to CBER, Pfizer will submit an official commitment in an amendment to the BLA. Pfizer stated that they envision this taking about a month to work out the testing procedures and another 2-3 months to validate the assay and CBER understood.

Pfizer asked if there are additional "roadblocks" on the BLA from this discipline and CBER replied that at this time there isn't, but there may still be issues as we complete our reviews.

END