



## 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 11, 2021; 12:00 PM - 12:39 PM EDT

### FDA Participants:

Anissa Cheung, Ph.D.  
Maryna Eichelberger, Ph.D.  
John Eltermann, R.Ph., M.S.  
Laura Gottschalk, Ph.D.  
Marion Gruber, Ph.D.  
Phil Krause, M.D., Ph.D.  
Robin Levis, Ph.D.  
Mary Malarkey  
Loris McVittie, Ph.D.  
Ramachandra Naik, Ph.D.  
Lori Peters, M.S.  
Kirk Prutzman, Ph.D.  
Carolyn Renshaw  
Michael Smith, Ph.D.  
Elizabeth Sutkowski, Ph.D.  
Jerry Weir, Ph.D.

### Applicant Participants:

Neda Aghajani Memar  
(b) (6)  
Donna Boyce  
Carmel Devlin  
Jennifer Huff  
(b) (6)  
Kevin Nepveux  
Amit Patel  
Paul Rohlfing  
Adrienne Kaye Stafford  
Nicholas Warne

**Background/Purpose of this call:**

To seek clarity on availability of EUA and BLA products and plans for distribution after licensure of COMIRNATY

**Teleconference Summary:**

FDA stated that the purpose of the call was to get a better idea regarding the post-licensure availability of the product [the current frozen formulation or Ready-To-Use (RTU) formulation] for which Pfizer is seeking licensure.

Pfizer stated that they intend to license and are prepared to launch the frozen formulation; however, they noted that they have a new United States Government (USG) contract for delivery of RTU formulation, which will be ready in October 2021. Pfizer is planning to file a BLA supplement for the RTU formulation. They clarified that they will not be able to provide BLA-labeled frozen formulation product immediately upon licensure. Some of Pfizer's EUA-labeled product is fully compliant with the BLA with the exception of the labeling, but can't be over-labeled with BLA-labeling because of the frozen storage conditions.

Pfizer is manufacturing both frozen formulation and RTU formulation DP in Pfizer, Puurs; they have just started manufacturing the RTU formulation in Pfizer, Kalamazoo. RTU formulation has EUA labels for use in individuals 12 years of age and older, and RTU products also can't also be over-labeled as these are also stored frozen; this may present a concern for use of the RTU product once such product is approved via a future BLA supplement.

With regard to the current original BLA under review, FDA asked how many lots or millions of doses Pfizer is planning to launch/release after approval. Pfizer replied that they have (b) (4) lots ((b) (4) million doses) in their control that are compliant with the BLA with the exception of the labeling. Also, Pfizer can get the inventory of the unused lots of vaccine distributed to the field for emergency use. Although these lots have EUA label, some of the lots are BLA-compliant, including being manufactured in facilities that will be licensed as part of the BLA. FDA committed to internally discussing the labelling issues for all of these lots and getting back to Pfizer on a possible plan forward.

A remaining issue is the need for lot release of lots under BLA. FDA can release these lots after a lot release protocol (LRP) is established. From now on, Pfizer will manufacture BLA-compliant product and provide lot release information.

Pfizer stated that they have fulfilled USG contract for frozen formulation. If approval of RTU formulation is delayed, Pfizer has the flexibility to continue manufacturing frozen formulation as it will be licensed and will be under Pfizer's control, including distribution.

Pfizer is planning to file EUA amendment for RTU formulation (for use in individuals 12 years of age and older) at the end of August 2021. FDA stated that we are prioritizing review of the BLA for the frozen formulation, and we will review the EUA amendment for the RTU formulation after taking action on the BLA.

Pfizer is planning to extend the expiration of the EUA product to 9 months per USG request.

FDA asked regarding the status of the IR for LRP. Pfizer replied that the LRP will be submitted today, and Pfizer knows how to send samples and submit protocol through gateway. However, Pfizer was concerned about the time CBER may take for testing (30-45 days), and pointed out that the 48-hour turnaround time for release under the EUA had been optimal. CBER clarified that under EUA, FDA is not releasing the product. Rather, lot information is submitted to FDA 48 hours prior to distribution. Further, FDA replied that we can't commit to 48-hour turnaround, but we understand the urgency and need to expedite and agree that 30-45 days is too long. FDA will work with Pfizer and can establish concurrent testing, i.e., testing concurrently with Pfizer to further reduce time to release. Pfizer understood and agreed.

For FDA's question regarding how Pfizer will supply the BLA-approved product to physicians, Pfizer replied that it will be achieved by some kind of communication.

**Post-Teleconference Note:**

An additional teleconference was held at 12:30 PM on Thursday, August 12, 2021, between management from CBER and Pfizer and it was decided that Pfizer will draft a letter for CBER review for inclusion in the cartons for distribution that describes the product.

**END**