



Teleconference Summary

Meeting date & time: May 6, 2021, 1:00 – 1:30 PM

Submission: EUA 27034.132

Product name: Human Coronavirus mRNA Vaccine (SARS-CoV-2 Spike Protein; BNT162b2) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol) (Pfizer-BioNTech COVID-19 Vaccine)

Proposed indication: Active immunization against COVID-19 in adults 12 years of age and older

Sponsor: Pfizer, Inc. (in partnership with BioNTech Manufacturing GmbH)

SUBJECT: Teleconference to discuss inclusion of syncope language in the Fact Sheet for Vaccination Providers-Full EUA Prescribing Information

CBER Participants

Marie Allende, MD
Doran Fink, MD, PhD
Laura Gottschalk, PhD
Marion Gruber, PhD
Philip Krause, MD
Lucia Lee, MD
Ramachandra Naik, PhD
Kirk Prutzman, PhD
CAPT Michael Smith, PhD

Pfizer-BioNTech Participants:

Bill Gruber, MD
John Perez, MD
Rob Maroko, MD
Susan Mather, MD
Donna Boyce
Elisa Harkins Tull
Carmel Devlin

Background:

Reference is made to the following:

- The revised Fact Sheet for Vaccination Providers-Full EUA PI that addresses CBER's April 30, 2021 was submitted to EUA 27034 in amendment 160 on May 3, 2021.
- CBER sent comments on May 5, 2021 regarding including syncope-related text under Warnings in Fact Sheet for Vaccination Providers-Full EUA PI.
- On May 6, 2021, Pfizer requested a teleconference (in email from Pfizer's Donna Boyce to FDA's Dr. Marion Gruber).

Teleconference Summary:

At the beginning of the meeting, FDA stated that episodes of syncope were observed in adolescents 12 through 15 years of age in the C4591001 clinical trial. Thus, our reason for including this in the current Fact Sheet for Vaccination Providers-Full EUA PI is 2-fold - (a) this observation has been made in the clinical trial (two cases; one in the vaccine group Subject 10071476 and the other in the placebo group Subject 11311280), and (b) there is the more general concern about immunization related stress responses in the adolescents. Therefore, this statement should be incorporated in the Fact Sheet for Vaccination Providers-Full EUA PI now as part of the authorization of the EUA amendment in adolescents 12 through 15 years of age. Pfizer provided additional clarification regarding the syncope cases observed in the clinical trial. Pfizer stated that there was only one real case of syncope observed in the clinical trial and it was considered unrelated. Therefore, Pfizer argued against including the syncope language in the Fact Sheet for Vaccination Providers-Full EUA PI as the inclusion may discourage adolescents receiving the vaccine. However, Pfizer proposed an alternative general statement "In adolescents, syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid fainting injury. Vaccinees should be observed for at least 15 minutes after vaccine administration." FDA asked Pfizer to submit the revised Fact Sheet for Vaccination Providers-Full EUA PI that includes the proposed language for syncope, and we will review and provide comments. Pfizer agreed.

END