Our Reference: IND 19736

AGREED INITIAL
PEDIATRIC STUDY PLAN-AGREEMENT
April 23, 2021

BioNTech SE/Pfizer, Inc.
Attention: Neda Aghajani Memar
235 East 42nd Street, 219/9/69
New York, NY 10017

Dear Ms. Aghajani Memar:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for "Human Coronavirus mRNA Vaccines (SARS-CoV-2 Spike Protein; BNT162a1 (uRNA; variant RBL063.3); BNT162b1 (modRNA; variant RBP020.3); BNT162b2 (modRNA; variant RBP020.2); BNT162c2 (saRNA; variant RBS004.2)) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol)."

We also refer to your amendment submitted and received on April 2, 2021, containing your final Agreed Initial Pediatric Study Plan (iPSP) as requested in the March 24, 2021 correspondence from the Agency.

We have completed our review of your Agreed iPSP and agree with your planned pediatric study and your plan to request a deferral of the pediatric assessment for the pediatric population 0 to <16 years of age.

This agreement does not necessarily imply agreement with other contents of the document in its entirety.

Please be advised that this agreement with your Agreed iPSP, and acknowledgment of your intention to request a deferral as stated above, does not constitute the "granting" of such a deferral. This can only occur at such time if/when this investigational product is licensed. A copy of your Agreed iPSP must be included in Module 1 of your Biologics License Application.

In the event that it becomes necessary to make any changes to this "Agreed iPSP" before submission of your Biologics License Application, please contact the Regulatory Project Manager to discuss the appropriate mechanisms for submitting this to FDA and for instructions on identifying your submission in order to ensure timely review. FDA must agree to any amendments to an Agreed iPSP.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

If you have any questions, please contact the Regulatory Project Manager, Ramachandra Naik, Ph.D., by email at ramachandra.naik@fda.hhs.gov.

Sincerely,

Doran Fink -S

Digitally signed by Doran Fink -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Doran Fink -S, 0.9.2342.19200300.100.1.1=0013724088
Date: 2021.04.23 07:58:47 -04'00'

Doran L. Fink, M.D., Ph.D.
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research