21. Name of Sponsor
BioNTech SE

2. Date of Submission (mm/dd/yyyy)
04/16/2021

4. Telephone Number (Include country code if applicable and area code)
215-280-5503

6. IND Number (If previously assigned)
019736

6A. IND Number (If previously assigned)

5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)
COVID-19 Vaccine (BNT162, PF-07302048)

7A. (Proposed) Indication for Use
Prophylactic immunization against COVID-19 in adults ≥16 years of age

Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes No

Does this product have an FDA Orphan Designation for this indication? Yes No

If yes, provide the Orphan Designation number for this indication:

7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)

8. Phase of Clinical Investigation to be conducted
Phase 1 ✔ Phase 2 ✔ Phase 3 Other (Specify):


BB-IND 013812, BB-IND 013278, BLA 125549

10. IND submission should be consecutively numbered. The initial IND should be numbered “Serial number: 0000.” The next submission (e.g., amendment, report, or correspondence) should be numbered “Serial Number: 0001.” Subsequent submissions should be numbered consecutively in the order in which they are submitted.

Serial Number
0 2 9 5

11. This submission contains the following (Select all that apply)

- Initial Investigational New Drug Application (IND)
- Request for Reactivation or Reinstatement
- Development Safety Update Report (DSUR)
- Response to Clinical Hold
- Annual Report
- Other (Specify):

12. For Originals, is the product a combination product (21 CFR 3.2(e))? Yes No

13. Select the following only if applicable. (Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)

- Expanded Access Use, 21 CFR 312.300
- Intermediate Size Patient Population, 21 CFR 312.315
- Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp

DDR Receipt Stamp

Division Assignment

IND Number Assigned
14. Contents of Application – This application contains the following items (Select all that apply)

- 1. Form FDA 1571 (21 CFR 312.23(a)(1))
- 2. Table of Contents (21 CFR 312.23(a)(2))
- 3. Introductory statement (21 CFR 312.23(a)(3))
- 4. General Investigational plan (21 CFR 312.23(a)(3))
- 5. Investigator’s brochure (21 CFR 312.23(a)(5))
- 6. Protocol (21 CFR 312.23(a)(6))
  - a. Study protocol (21 CFR 312.23(a)(6))
  - b. Investigator data (21 CFR 312.23(a)(6)(ii)(b)) or completed Form FDA 1572
  - c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
- 6. Protocol (Continued)
  - d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
- 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7))
  - Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e))
- 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
- 9. Previous human experience (21 CFR 312.23(a)(9))
- 10. Additional information (21 CFR 312.23(a)(10))
- 11. Biosimilar User Fee Cover Sheet (Form FDA 3792)
- 12. Clinical Trials Certification of Compliance (Form FDA 3674)

15. Is any part of the clinical study to be conducted by a contract research organization? ☑ Yes ☑ No

If Yes, will any sponsor obligations be transferred to the contract research organization? ☑ Yes ☑ No

If Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred (use continuation page).

16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

Özlem Türeci, MD, Chief Medical Officer, BioNTech SE

17. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug

Özlem Türeci, MD, Chief Medical Officer, BioNTech SE

I agree not to begin clinical investigations until 30 days after FDA’s receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

18. Name of Sponsor or Sponsor’s Authorized Representative

Neda Aghajani Memar, Pharm.D., Director, Pfizer Global Regulatory Affairs - Vaccines

19. Telephone Number (Include country code if applicable and area code)

212-733-2613

20. Facsimile (FAX) Number (Include country code if applicable and area code)

(845) 474-3500

21. Address

Address 1 (Street address, P.O. box, company name c/o)

235 East 42nd Street

Address 2 (Apartment, suite, unit, building, floor, etc.)

219/9/69

City

New York

State/Province/Region

NY

Country

United States of America

ZIP or Postal Code

10017

22. Email Address

Neda.AghajaniMemar@pfizer.com

23. Date of Sponsor’s Signature (mm/dd/yyyy)

04/15/2021

24. Name of Countersigner

25. Address of Countersigner

Address 1 (Street address, P.O. box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

State/Province/Region

Country

United States of America

ZIP or Postal Code

26. Email Address

27. Signature of Sponsor or Sponsor’s Authorized Representative

Neda Aghajani Memar

Sign

28. Signature of Countersigner

Sign

WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).
The information below applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
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