Section 1 - 125742/0/0

- 1.3.4 Financial Certification and Disclosure
  - [0001] Financial Certification and Disclosure - Summary Note
  - [0001] Financial Certification and Disclosure - Bias Statement
  - [0001] Financial Certification and Disclosure - FDA Form 3454
  - [0001] Financial Certification and Disclosure - FDA Form 3455
- 1.3.5 Patent and Exclusivity
  - 1.3.5.3 Exclusivity Claim
    - [0001] Exclusivity Claim
- 1.4 References
  - 1.4.3 List of Authorized Persons to Incorporate By Reference
    - [0001] Letter of Authorization to US Agent
- 1.6 Meetings
  - 1.6.3 Correspondence Regarding Meetings
    - [0001] Correspondence Regarding Meetings
- 1.7 Fast Track
  - 1.7.4 Correspondence Regarding Fast Track/Rolling Review
    - [0001] Grant Fast Track Designation Letter
- 1.9 Pediatric Administrative Information
  - 1.9.2 Request for Deferral of Pediatric Studies
    - [0001] Request for Deferral of Pediatric Studies
  - 1.9.4 Proposed Pediatric Study Request and Amendments
    - [0001] Agreed Initial Pediatric Study Plan

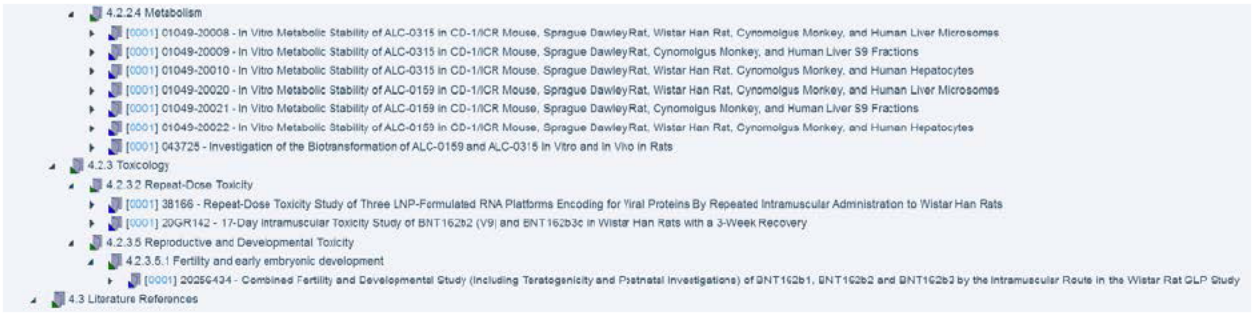

- 1.9.4 Proposed Pediatric Study Request and Amendments
  - [0001] Agreed Initial Pediatric Study Plan

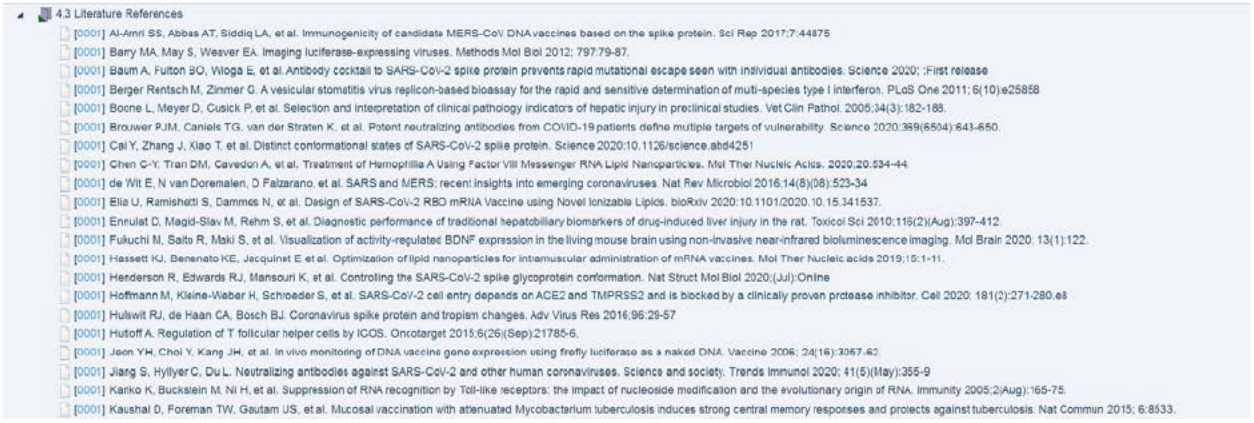
- 1.9.6 Other Correspondence Regarding Pediatric Exclusivity or Study Plans
  - [0001] Agreed iPSP Agreement Letter
- 1.12 Other Correspondence
  - 1.12.5 Request for a Waiver
    - [0001] Waiver Request for FDA Designated Suffix
- 2 Common Technical Document Summaries
- **4 Nonclinical Study Reports**
- 5 Clinical Study Reports

Section 2 - 125742/0/0

- [0001] Pharmacology Tabulated Summary
- 2.6.4 Pharmacokinetics Written Summary
  - [0001] Pharmacokinetics Written Summary
- 2.6.5 Pharmacokinetics Tabulated Summary
  - [0001] Pharmacokinetics Tabulated Summary
- 2.6.6 Toxicology Written Summary
  - [0001] Toxicology Written Summary
- 2.6.7 Toxicology Tabulated Summary
  - [0001] Toxicology Tabulated Summary
- 2.7 Clinical Summary
  - 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods
    - [0001] Summary of Biopharmaceutic Studies and Associated Analytical Methods
  - 2.7.3 Summary of Clinical Efficacy
    - [0001] Summary of Clinical Efficacy
  - 2.7.4 Summary of Clinical Safety
    - [0001] Summary of Clinical Safety
  - 2.7.5 Literature-References
    - [0001] Literature References
  - 2.7.6 Synopses of Individual Studies
    - [0001] Synopses of Individual Studies
- **4 Nonclinical Study Reports**
- 5 Clinical Study Reports

# Section 4 - 125742/0/0

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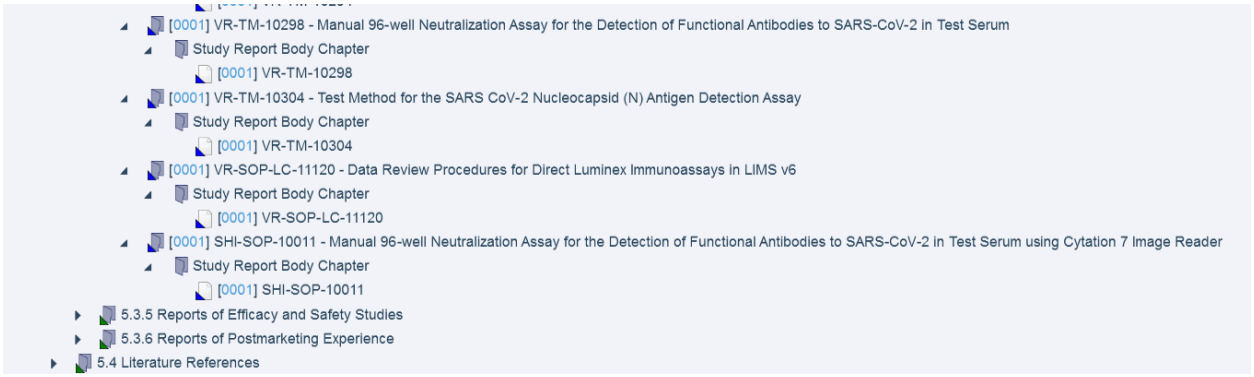
# Section 5.3.1 - 125742/0/0



[0001] VR-MQR-10211 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Sera
Study Report Body Chapter
[0001] VR-MQR-10211
[0001] VR-MQR-10211-ATT01
[0001] VR-MQR-10212 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Sera
Study Report Body Chapter
[0001] VR-MQR-10212
[0001] VR-MQR-10212-ATT01
[0001] VR-MQR-10214 - Qualification of the SARS-CoV-2 mNeonGreen Virus Miconeutralization Assay
Study Report Body Chapter
[0001] VR-MQR-10214
[0001] VR-MQR-10214-ATT01
[0001] VR-MQR-10214-ATT02
[0001] VR-MQR-10214-ATT03
[0001] VR-TM-10293 - Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Serum
Study Report Body Chapter
[0001] VR-TM-10293
[0001] VR-TM-10294 - Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Serum
Study Report Body Chapter
[0001] VR-TM-10294
[0001] VR-TM-10298 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum
Study Report Body Chapter


[0001] VR-TM-10298 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum
Study Report Body Chapter
[0001] VR-TM-10298
[0001] VR-TM-10304 - Test Method for the SARS CoV-2 Nucleocapsid (N) Antigen Detection Assay
Study Report Body Chapter
[0001] VR-TM-10304
[0001] VR-SOP-LC-11120 - Data Review Procedures for Direct Luminex Immunoassays in LIMS v6
Study Report Body Chapter
[0001] VR-SOP-LC-11120
[0001] SHI-SOP-10011 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum using Cytation 7 Image Reader
Study Report Body Chapter
[0001] SHI-SOP-10011
5.3.5 Reports of Efficacy and Safety Studies
5.3.6 Reports of Postmarketing Experience
5.4 Literature References

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***THIS REPORT MAY CONTAIN CONFIDENTIAL INFORMATION***

STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 13-MAY-2021 | Y | | Letter. Acknowledgement Letter - Rolling Review ( DICKERSON, DAVID ) | | |
| 18-MAY-2021 | Y | | Telecon. Information Request - IR RE datasets. ( SMITH, MICHAEL ) | | |
| 20-MAY-2021 | Y | | Telecon. Information Request - Four facility questions from DMPQ and a request for a t-con on 5/25/21 or 5/26/21 to discuss production schedules and the shutdown activities planned for the Puurs, Belgium site. ( SMITH, MICHAEL ) | | |
| 03-JUN-2021 | Y | | Meeting Summary. First Committee Meeting - First Committee Meeting Summary ( NAIK, RAMACHANDRA ) | | |
| 08-JUN-2021 | Y | | Telecon. Information Request - Three clinical questions. ( SMITH, MICHAEL ) | | |
| 09-JUN-2021 | Y | | Telecon. Information Request - IR for PREA dates for deferred pediatric studies. ( SMITH, MICHAEL ) | | |
| 17-JUN-2021 | Y | | Memo. Other - Permission to release License number to applicant prior to approval. ( JONECKIS, CHRISTOPHER ) | | |
| 25-JUN-2021 | Y | | Telecon. Information Request - IR from DBSQC regarding the lot release protocol (LRP) template and samples & reagents. ( SMITH, MICHAEL ) | | |
| 25-JUN-2021 | Y | | Telecon. Information Request - IR regarding the document titled ¿bnt162-01-interim3-report-body¿. ( SMITH, MICHAEL ) | | |
| 29-JUN-2021 | Y | | Meeting Summary. Filing Meeting Summary - Summary of the June 29, 2021 Filing Meeting. The BLA is fileable. ( NAIK, RAMACHANDRA ) | | |
| 29-JUN-2021 | Y | | Telecon. Information Request - Clinical IR regarding Study C4591001. ( SMITH, MICHAEL ) | | |
| 01-JUL-2021 | Y | | Memo. Filing Checklist/RPM - RPM Filing Checklist - the application is fileable. ( GOTTSCHALK, LAURA ) | | |
| 02-JUL-2021 | Y | | Memo. Committee Memo/APLB - PNR COMIRNATY: ACCEPTABLE ( ELEKWACHI, OLUCHI ) | | |
| 02-JUL-2021 | Y | | Telecon. Advice - Advice: Pfizer¿s assumption as outlined in Elisa Harkins June 29, 2021 e-mail RE the bnt162-01-interim3-report-body are correct. ( SMITH, MICHAEL ) | | |
| 02-JUL-2021 | Y | | Telecon. Information Request - Comments regarding CMC information and categorical exclusion for an environment analysis ( NAIK, RAMACHANDRA ) | | |
| 06-JUL-2021 | Y | | Telecon. PNR Acceptance / Advice - The Applicant was informed that their proprietary name "COMIRNATY" is acceptable. ( SMITH, MICHAEL ) | | |
| 06-JUL-2021 | Y | | Telecon. Information Request - Clinical IR RE the document titled ¿c4591001-interim-mth6-report-body.pdf." ( SMITH, MICHAEL ) | | |
| 09-JUL-2021 | Y | | Telecon. Information Request - IR RE the validation of the RNA Integrity by capillary gel electrophoresis (CGE) method. ( SMITH, MICHAEL ) | | |
| 13-JUL-2021 | Y | | Telecon. Information Request - OBE IR RE adding myocarditis and pericarditis to the PVP. ( SMITH, MICHAEL ) | | |
| 13-JUL-2021 | Y | | Telecon. Information Request - DVP IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative ( NAIK, RAMACHANDRA ) | | |
| 15-JUL-2021 | Y | | Letter. Filing Notification Letter / No Deficiencies Identified - Filing Notification<br>No Deficiencies Identified ( SMITH, MICHAEL ) | | |
| 15-JUL-2021 | Y | | Telecon. Information Request - IR RE Study C4591007; please provide updated goal dates for final protocol submission. ( SMITH, MICHAEL ) | | |
| 15-JUL-2021 | Y | | Meeting Summary. Committee Meeting Summary - Summary of the July 15, 2021 Monthly Committee Meeting. ( GOTTSCHALK, LAURA ) | | |
| 15-JUL-2021 | Y | | Telecon. Information Request - F/U IR RE updated PVP by 7/29/21. ( SMITH, MICHAEL ) | | |
| 16-JUL-2021 | Y | | Telecon. Information Request - DBSQC IR regarding lot release protocol template and drug substance handling instructions. ( GOTTSCHALK, LAURA ) | | |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 16-JUL-2021 | Y | | Telecon. Information Request - DBSQC IR regarding (b) (4) and (b) (4) test methods ( GOTTSCHALK, LAURA ) | | |
| 19-JUL-2021 | Y | | Telecon. Advice - US license number 2229 was provided to the applicant prior to approval in response to the request included in the cover letter of the first roll of their BLA on May 6, 2021. ( NAIK, RAMACHANDRA ) | | |
| 20-JUL-2021 | Y | | Memo. Review - CDISC validation results and discussion ( BALDWIN, BRENDA ) | | |
| 20-JUL-2021 | Y | | Telecon. Information Request - Clinical IR for a revised pediatric plan to include study C4591007 for subject 6 months to 11 years of age and proposal of another study to enroll infants <6 months of age. ( NAIK, RAMACHANDRA ) | | |
| 22-JUL-2021 | Y | | Telecon. Information Request - Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments ( GOTTSCHALK, LAURA ) | | |
| 26-JUL-2021 | Y | | Telecon. Information Request - Clinical IR regarding the disposition of participants in safety populations who experienced pregnancy. ( GOTTSCHALK, LAURA ) | | |
| 26-JUL-2021 | Y | | Telecon. Information Request - DMPQ IR regarding manufacturing and equipment ( GOTTSCHALK, LAURA ) | | |
| 27-JUL-2021 | Y | | Telecon. Information Request - Clinical IR RE vaccine effectiveness ( SMITH, MICHAEL ) | | |
| 27-JUL-2021 | Y | | Telecon. Information Request - Third clinical IR RE vaccine effectiveness. ( SMITH, MICHAEL ) | | |
| 28-JUL-2021 | Y | | Telecon. Labeling Target Closure / Labeling via FAX/e-mail - First set of labeling comments regarding the PI ( NAIK, RAMACHANDRA ) | | |
| 28-JUL-2021 | Y | | Telecon. Information Request - OBE IR regarding postmarketing safety study(ies) ( NAIK, RAMACHANDRA ) | | |
| 29-JUL-2021 | Y | | Telecon. Information Request - Clinical IR regarding safety analysis for two age groups ( GOTTSCHALK, LAURA ) | | |
| 02-AUG-2021 | Y | | Telecon. Information Request - Questions regarding the Validation Report VR-MVR-10077 ( SMITH, MICHAEL ) | | |
| 02-AUG-2021 | Y | | Telecon. Information Request - Five questions regarding validation of assay methods and lot release. ( SMITH, MICHAEL ) | | |
| 03-AUG-2021 | Y | | Telecon. Information Request - Six CMC-related questions. ( SMITH, MICHAEL ) | | |
| 03-AUG-2021 | Y | | Telecon. Information Request - Two clinical/stats questions regarding July 26, 2021, submission and SAS programs. ( SMITH, MICHAEL ) | | |
| 04-AUG-2021 | Y | | Telecon. Information Request - Two questions regarding the potency assay for determination of (b) (4) by (b) (4) . ( SMITH, MICHAEL ) | | |
| 04-AUG-2021 | Y | | Telecon. Information Request - F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021. ( SMITH, MICHAEL ) | | |
| 04-AUG-2021 | Y | | Telecon. Information Request - Secondary e-mail with attachment RE 8/4/21 F/U LRP comments. ( SMITH, MICHAEL ) | | |
| 05-AUG-2021 | Y | | Telecon. Advice - Informed the applicant regarding the PROPER NAME for their product in this BLA. ( GOTTSCHALK, LAURA ) | | |
| 05-AUG-2021 | Y | | Telecon. Information Request - 11 facility questions. ( SMITH, MICHAEL ) | | |
| 05-AUG-2021 | Y | | Telecon. Information Request - Four questions regarding the diluent. ( SMITH, MICHAEL ) | | |
| 05-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 2nd round of PI labeling comments. ( SMITH, MICHAEL ) | | |
| 06-AUG-2021 | Y | | Letter. UNII Code Notification - Unique Ingredient Identifier (UNII) Code Assignment ( SMITH, MICHAEL ) | | |
| 06-AUG-2021 | Y | | Memo. Committee Memo/APLB - APLB BLA LR ( ELEKWACHI, OLUCHI ) | | |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 06-AUG-2021 | Y | Y | Memo. Review - OBE/DE Pharmacovigilance Review ( THOMPSON, DEBORAH ) | | |
| 06-AUG-2021 | Y | | Telecon. Information Request - IR RE two DP documents. ( SMITH, MICHAEL ) | | |
| 06-AUG-2021 | Y | | Telecon. Information Request - Three DBSQC questions RE measurement of (b) (4) using the (b) (4) procedures. ( SMITH, MICHAEL ) | | |
| 09-AUG-2021 | Y | | Telecon. Advice - Advice RE submitting samples, LRP and distribution of EUA and BLA labeled product after COMIRNATY is licensed. ( SMITH, MICHAEL ) | | |
| 09-AUG-2021 | Y | | Telecon. Information Request - Clinical IR RE sequencing data. ( SMITH, MICHAEL ) | | |
| 09-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - Comments on the Carton and Container labels ( SMITH, MICHAEL ) | | |
| 10-AUG-2021 | Y | | Telecon. Information Request - Second OBE IR regarding safety-related postmarketing studies. ( NAIK, RAMACHANDRA ) | | |
| 10-AUG-2021 | Y | | Telecon. Information Request - One testing related question from DBSQC. ( SMITH, MICHAEL ) | | |
| 11-AUG-2021 | Y | | Telecon. Information Request - One question from DMPQ regarding the diluent that is to be provided with the vaccine. ( SMITH, MICHAEL ) | | |
| 11-AUG-2021 | Y | | Telecon. Other - This teleconference between CBER and Pfizer was to seek clarity on availability of EUA and BLA products and plans for distribution after licensure of COMIRNATY. ( SMITH, MICHAEL ) | | |
| 12-AUG-2021 | Y | | Memo. Committee Memo/Require Pre-Approval Inspection ( CHEUNG, ANISSA ) | | |
| 12-AUG-2021 | Y | | Telecon. Other - Teleconference between CBER and Pfizer to receive clarification on how EUA lots and BLA lots will be indentified. ( NAIK, RAMACHANDRA ) | | |
| 13-AUG-2021 | Y | Y | Memo. Committee Memo/BIMO - BIMO Discipline Review Memo ( CHUN, HAECIN ) | | |
| 13-AUG-2021 | Y | | Memo. Request For Compliance Check - Request for Compliance check. ( ZUBKOVA, IRYNA ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - Three clinical questions. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - DBQSC IR LRP and testing. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - 7 facility questions from the DMPQ team. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - A clinical IR was sent on 13AUG21 and Pfizer had a clarification question. This IR t-con was in response to the F/U clarification question. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 3rd set of PI labeling comments. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - One clinical question. ( SMITH, MICHAEL ) | | |
| 13-AUG-2021 | Y | | Telecon. Information Request - IR RE PMR's and PMC's. ( SMITH, MICHAEL ) | | |
| 16-AUG-2021 | Y | | Telecon. Information Request - DMPQ IR RE (b) (4) (b) (4) . ( SMITH, MICHAEL ) | | |
| 16-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - Second set of comments and questions on the carton and container labels. ( SMITH, MICHAEL ) | | |
| 16-AUG-2021 | Y | | Telecon. Information Request - Teleconference regarding measurement of (b) (4) . Pfizer commits to implement (b) (4) testing method on (b) (4) . ( SMITH, MICHAEL ) | | |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 16-AUG-2021 | Y | | Telecon. Information Request - Please submit this same CMC stability information that was submitted to EUA 27034.260 to your BLA STN 125742 .0 so that we can consider a 9-month shelf-life for the licensed product. ( NAIK, RAMACHANDRA ) | | |
| 17-AUG-2021 | Y | | Memo. Lot Release Clearance Memo / Lot Release Clearance Request - Lot Release Clearance Request and Lot Release Clearance Memo. ( BESHIR, LEYLA ) | | |
| 17-AUG-2021 | Y | | Memo. Other; Non-proprietary name does not include a suffix - Justification memo regarding approving non-proprietary name without a suffix ( GRUBER, MARION ) | | |
| 17-AUG-2021 | Y | | Telecon. Other - The purpose of the teleconference between DMPQ and Pfizer was to discuss items 2b, 2c, 6 and 9c from the FDA form 483 for the Andover site. ( SMITH, MICHAEL ) | | |
| 17-AUG-2021 | Y | | Telecon. Information Request - Two questions from Xiao Wang regarding drug substance. ( SMITH, MICHAEL ) | | |
| 17-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 4th set of PI labeling comments. ( SMITH, MICHAEL ) | | |
| 17-AUG-2021 | Y | | Telecon. Information Request - Follow up IR RE PMR & PMC's commitments that were received in amendment 51 dated August 16, 2021. ( NAIK, RAMACHANDRA ) | | |
| 17-AUG-2021 | Y | | Telecon. Information Request - DVP IR regarding two questions on shelf life and date of manufacture. ( SMITH, MICHAEL ) | | |
| 18-AUG-2021 | Y | | Memo. Committee Memo/Review - DBSQC LRP template review memo ( ANDERSON, MARIE ) | | |
| 18-AUG-2021 | Y | Y | Memo. Committee Memo/Statistical Non-Clinical - Statistical review memo for non-clinical data ( TANG, XINYU ) | | |
| 18-AUG-2021 | Y | | Telecon. Advice - Pfizer e-mailed clarification questions on August 18, 2021, to DVP's two DS questions dated August 17, 2021. This e-mail was guidance in response to their clarification questions. ( SMITH, MICHAEL ) | | |
| 18-AUG-2021 | Y | | Telecon. Information Request - Two DBSQC questions on amendments 54 and 50 RE (b) (4) testing and specific parameters/instructions for (b) (4) (b) (4) test method. ( SMITH, MICHAEL ) | | |
| 18-AUG-2021 | Y | | Telecon. Information Request - DVP follow-up response to Pfizer August 18, 2021, clarification questions regarding DVP's August 17, 2021, IR on shelf life and date of manufacture. ( SMITH, MICHAEL ) | | |
| 18-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 5th set of PI labeling comments. ( SMITH, MICHAEL ) | | |
| 18-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 3rd set of comments on the carton and container labels. ( GOTTSCHALK, LAURA ) | | |
| 18-AUG-2021 | Y | | Telecon. Information Request - Identification of BLA-compliant lots and Letter to HCP. ( NAIK, RAMACHANDRA ) | | |
| 19-AUG-2021 | Y | Y | Memo. Committee Memo/Statistical Clinical - Statistical memo for clinical efficacy data ( HUANG, LEI ) | | |
| 19-AUG-2021 | Y | Y | Memo. Committee Memo/Statistical Clinical - Statistical review for safety data. ( YANG, YE ) | | |
| 19-AUG-2021 | Y | | Memo. Compliance Check Acceptable - Compliance check is acceptable. ( DECIERO, DANIEL ) | | |
| 19-AUG-2021 | Y | | Telecon. Information Request - IR RE PMR's and PMC's that were listed in amendment 51. ( SMITH, MICHAEL ) | | |
| 19-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 6th set of PI labeling comments. ( GOTTSCHALK, LAURA ) | | |
| 19-AUG-2021 | Y | | Telecon. Information Request - IR RE PMC Study Completion Date and Final Report Submission date for PMC Study C4591014. ( SMITH, MICHAEL ) | | |
| 20-AUG-2021 | Y | | Memo. Committee Memo/Labeling - Review Memo: Containers, Cartons, Sticker, Stamp ( STEWART, DAPHNE ) | | |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 20-AUG-2021 | Y | | Memo. Other - CONFIDENTIAL - DO NOT POST TO THE WEB CBER Laboratory Quality Product Testing Plan ( ANDERSON, MARIE ) | | |
| 20-AUG-2021 | Y | Y | Memo. Review - Pharmacovigilance Plan Review; Addendum Memorandum ( WELSH, KERRY ) | | |
| 20-AUG-2021 | Y | | Memo. Test Results - In-support (b) (4) Test Results ( KONG, HYESUK ) | | |
| 20-AUG-2021 | Y | | Memo. Test Results - Test memo for (b) (4) ( WANG, HSIAOLING ) | | |
| 20-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 7th set of PI comments and shell table. ( GOTTSCHALK, LAURA ) | | |
| 20-AUG-2021 | Y | | Telecon. Information Request / Advice - Lot Numbers for the COVID Launch Lots ( NAIK, RAMACHANDRA ) | | |
| 20-AUG-2021 | Y | | Telecon. Information Request - CBER comments regarding label for identification of BLA lots and Dear HCP Letter ( NAIK, RAMACHANDRA ) | | |
| 20-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - Comment regarding vial label to include the name of the diluent on vial labels. ( GOTTSCHALK, LAURA ) | | |
| 21-AUG-2021 | Y | Y | Memo. Committee Memo/CMC - CMC Product Review Memo ( WANG, XIAO ) | | |
| 21-AUG-2021 | Y | Y | Memo. Committee Memo/CMC - DBSQC Analytical Review Memo ( YITBAREK, EMNET ) | | |
| 21-AUG-2021 | Y | | Telecon. Information Request - IR RE request to resubmit all PMR's and PMC's and a commitment to conduct them in the timeframe noted in an amendment to the BLA. Also, revised study completion date for study C4591007. ( SMITH, MICHAEL ) | | |
| 21-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - 8th set of PI labeling comments ( GOTTSCHALK, LAURA ) | | |
| 21-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - The Applicant was notified that the Carton and Container labels submitted in Amendment 63 dated August 19, 2021, are considered the Final Draft Labels for approval. ( GOTTSCHALK, LAURA ) | | |
| 21-AUG-2021 | Y | | Telecon. Information Request - CBER comments regarding label for identification of BLA lots and Dear HCP Letter. ( NAIK, RAMACHANDRA ) | | |
| 21-AUG-2021 | Y | | Telecon. Advice - The Applicant was notified that there are no additional comments on the Dear HCP letter submitted in Amendment 73 submitted August 21, 2021. ( NAIK, RAMACHANDRA ) | | |
| 22-AUG-2021 | Y | Y | Memo. Committee Memo/Postmarketing Safety Epidemiological - OBE Real World Evidence Memo ( LU, YUN ) | | |
| 22-AUG-2021 | Y | Y | Memo. Committee Memo/Review - DMPQ Review Memo - Recommend approval ( JONES, KATHLEEN ) | | |
| 22-AUG-2021 | Y | Y | Memo. Other - Employee/Officer List Memo ( GOTTSCHALK, LAURA ) | | |
| 22-AUG-2021 | Y | | Telecon. Labeling via FAX/e-mail - The Applicant was notified that the Package Insert submitted in Amendment 74 dated August 21, 2021, is considered the Final Draft Label for approval ( GOTTSCHALK, LAURA ) | | |
| 23-AUG-2021 | Y | Y | Letter. Approval - BLA Approval Letter ( SMITH, MICHAEL ) | | |
| 23-AUG-2021 | Y | Y | Memo. Committee Memo/SBRA - SBRA - Summary Basis for Regulatory Action ( NAIK, RAMACHANDRA ) | | |
| 23-AUG-2021 | Y | Y | Memo. Committee Memo/Toxicology - Committee Memo/Toxicology ( AL-HUMADI, NABIL ) | | |
| 23-AUG-2021 | Y | | Memo. Other - OCOD Transmittal Memo for web posting ( SMITH, MICHAEL ) | | |
| 23-AUG-2021 | Y | Y | Memo. Review - OBE Sentinel Sufficiency Assessment ( OBIDI, JOYCE ) | | |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 30-AUG-2021 | Y | | Telecon. Other - Amendment 125742.0.41 was reviewed in the DBSQC memo dated 08/20/2021. Pfizer's responses were acceptable. ( WANG, HSIAOLING ) | | |
| 30-AUG-2021 | Y | | Telecon. Other - Amendment 125742.0.60 was reviewed in the Andover 483 response memo. Pfizer's responses were acceptable. ( JONES, KATHLEEN ) | | |
| 01-SEP-2021 | Y | | Memo. Committee Memo/Labeling - RPM Labeling Review Memo ( GOTTSCHALK, LAURA ) | | |
| 02-SEP-2021 | Y | Y | Memo. Committee Memo/Clinical Review - Committee Memo/Clinical Review. Ann Schwartz and Lucia Lee contributed to this review memo. ( WOLLERSHEIM, SUSAN ) | | |
| 13-SEP-2021 | Y | Y | Memo. Committee Memo/Review / Benefit-Risk assessment - Benefit-Risk assessment review memo; Patrick Funk, Ph.D., and Osman N. Yogurtcu, Ph.D., also contributed to the review memo. ( YANG, HONG ) | | |
| 13-SEP-2021 | Y | | Memo. Committee Memo/Review - Documentation review memo. ( SMITH, MICHAEL ) | | |
| 30-SEP-2021 | Y | Y | Memo. Revised Post Lockdown / Committee Memo/Toxicology - Revised Post Lockdown/ Committee Memo/Toxicology/23-Aug-2021 ( AL-HUMADI, NABIL ) | | |
| 08-NOV-2021 | Y | Y | Memo. Revised Post Lockdown / Committee Memo/SBRA - Table 2 header and value for water in the table were changed. ( NAIK, RAMACHANDRA ) | | |
| 06-MAY-2021 | Y | | Original Application. For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older. | 06-MAY-2021 | 1067058 |
| 18-MAY-2021 | Y | | Amendment # 1. Second and final rolling piece to start the review clock. | 18-MAY-2021 | 1086158 |
| 19-MAY-2021 | Y | | Amendment # 2. Request for Proprietary Name Review | 19-MAY-2021 | 1087747 |
| 19-MAY-2021 | Y | | Amendment # 3. Response to May 18, 2021, clinical IR RE three dataset questions. | 19-MAY-2021 | 1088844 |
| 24-MAY-2021 | Y | | Amendment # 4. Response to DMPQ¿s May 20, 2021, IR RE four facilities questions and a request for a t-con on 5/25/21 or 5/26/21 to discuss production schedules and the shutdown activities planned for the Puurs, Belgium site. | 24-MAY-2021 | 1094917 |
| 07-JUN-2021 | Y | | Amendment # 5. COVID-19 case strain sequencing data. | 07-JUN-2021 | 1119355 |
| 16-JUN-2021 | Y | | Amendment # 6. Response to June 8, 2021, clinical IR on three clinical questions regarding datasets and the PI. | 16-JUN-2021 | 1137474 |
| 17-JUN-2021 | Y | | Amendment # 7. Response to June 9, 2021, clinical IR requesting dates for PREA deferred studies. | 17-JUN-2021 | 1139420 |
| 02-JUL-2021 | Y | | Amendment # 8. Response to June 29, 2021, clinical IR RE latest date of randomization for participants included in the reactogenicity subset for Study C4591001. | 02-JUL-2021 | 1168170 |
| 02-JUL-2021 | Y | | Amendment # 9. Response to June 25, 2021, clinical IR regarding IR regarding the document titled ¿bnt162-01-interim3-report-body¿ | 02-JUL-2021 | 1168177 |
| 09-JUL-2021 | Y | | Amendment # 10. Response to DBSQC¿s June 25, 2021, IR regarding the lot release protocol (LRP) template and samples & reagents. | 09-JUL-2021 | 1183932 |
| 15-JUL-2021 | Y | | Amendment # 11. Response to DVP¿s July 13, 2021, IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative. | 15-JUL-2021 | 1199647 |
| 16-JUL-2021 | Y | | Amendment # 12. Response to July 6, 2021, clinical IR regarding IR regarding the document titled ¿c4591001-interim-mth6-report-body.pdf.¿ | 16-JUL-2021 | 1201833 |
| 19-JUL-2021 | Y | | Amendment # 13. The applicant waives their rights to the mid- and late-cycle review meetings for BLA 125742. | 19-JUL-2021 | 1204967 |
| 20-JUL-2021 | Y | | Amendment # 14. | 20-JUL-2021 | 1207929 |

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 23-JUL-2021 | Y | | Amendment # 15. Response to July 15, 2021, Clinical IR RE study C4591007 to provide updated goal dates for final protocol submission and July 20, 2021 follow-up Clinical IR for a revised pediatric plan to include study C4591007 for subject 6 months to 11 years of age and proposal of another study to enroll infants <6 months of age. | 23-JUL-2021 | 1217479 |
| 23-JUL-2021 | Y | | Amendment # 16. Response to July 9, 2021 IR RE the validation of the RNA Integrity by capillary gel electrophoresis method. | 23-JUL-2021 | 1217492 |
| 26-JUL-2021 | Y | | Amendment # 17. Responses to questions 3-5 of July 22, 2021 clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments. | 26-JUL-2021 | 1221258 |
| 28-JUL-2021 | Y | | Amendment # 18. Responses to questions 1-2 of July 22, 2021 clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments. | 28-JUL-2021 | 1227088 |
| 28-JUL-2021 | Y | | Amendment # 19. Response to July 2, 2021 DVP IR regarding 18 question on product related issues and categorical exclusion for an environmental assessment. | 28-JUL-2021 | 1227383 |
| 30-JUL-2021 | Y | | Amendment # 22. Response to July 27, 2021 third Clinical IR RE vaccine effectiveness. | 30-JUL-2021 | 1233501 |
| 30-JUL-2021 | Y | | Amendment # 24. Response to July 26, 2021 DMPQ IR regarding manufacturing and equipment. | 30-JUL-2021 | 1236249 |
| 02-AUG-2021 | Y | | Amendment # 25. Response to the observations contained in the FDA form 483 that was issued for the pre-approval inspection of the Pfizer Andover facility. | 02-AUG-2021 | 1236634 |
| 02-AUG-2021 | Y | | Amendment # 26. Response to July 29, 2021 clinical IR regarding safety analysis for two age groups. | 02-AUG-2021 | 1237210 |
| 02-AUG-2021 | Y | | Amendment # 27. Response to 7/28/2021 first set of labeling comments regarding the PI. | 02-AUG-2021 | 1237211 |
| 02-AUG-2021 | Y | | Amendment # 28. Response to comment 5b of July 22, 2021 clinical-statistical IR. | 02-AUG-2021 | 1237740 |
| 03-AUG-2021 | Y | | Amendment # 29. Follow-up response (remaining supporting documents to response 10) to July 26, 2021 DMPQ IR regarding manufacturing and equipment. | 03-AUG-2021 | 1241021 |
| 03-AUG-2021 | Y | | Amendment # 30. Response to OBE¿s July 28, 2021 comments regarding post marketing observational safety study(ies) to assess myocarditis/pericarditis following administration of COMIRNATY as well as providing plans to characterize subclinical cases of myocarditis. | 03-AUG-2021 | 1241533 |
| 05-AUG-2021 | Y | | Amendment # 31. Response to DVP and OBE Questions regarding the Validation Report VR-MVR-10077. | 05-AUG-2021 | 1247205 |
| 05-AUG-2021 | Y | | Amendment # 32. Response to clinical and stats IR¿s fromJuly 22nd and August 4th regarding shell tables and two additional clinical/stats questions regarding July 26, 2021, submission and SAS program. | 05-AUG-2021 | 1247821 |
| 06-AUG-2021 | Y | | Amendment # 33. Responses to DVP¿s six CMC-related questions from August 3, 2021. | 06-AUG-2021 | 1249468 |
| 06-AUG-2021 | Y | | Amendment # 34. Responses to August 4, 2021, IR RE two questions regarding the potency assay for determination of (b) (4) by (b) (4) . | 06-AUG-2021 | 1249503 |
| 09-AUG-2021 | Y | | Amendment # 35. Response to DBSQC and Xiao Wang's August 2, 2021, questions regarding validation of assay methods and lot release. | 09-AUG-2021 | 1252956 |
| 09-AUG-2021 | Y | | Amendment # 36. Response to four questions regarding the diluent dated August 5, 2021. | 09-AUG-2021 | 1252957 |
| 09-AUG-2021 | Y | | Amendment # 37. Response to July 22nd Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001. | 09-AUG-2021 | 1252966 |
| 09-AUG-2021 | Y | | Amendment # 38. Revised PI labeling in response to August 5, 2021, second round of labeling comments. | 09-AUG-2021 | 1253712 |
| 10-AUG-2021 | Y | | Amendment # 39. Response to Xiao Wang¿s August 6, 2021, questions regarding two drug product (DP) documents. | 10-AUG-2021 | 1258976 |

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Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 11-AUG-2021 | Y | | Amendment # 40. Response to August 4, 2021, F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021. | 11-AUG-2021 | 1271302 |
| 11-AUG-2021 | Y | | Amendment # 41. Response to one testing related question from DBSQC on August 10, 2021. | 11-AUG-2021 | 1271303 |
| 11-AUG-2021 | Y | | Amendment # 42. Response to August 10, 2021, second OBE IR regarding safety-related postmarketing studies. | 11-AUG-2021 | 1271308 |
| 11-AUG-2021 | Y | | Amendment # 43. Responses to DMPQ¿s August 5, 2021 11 facilities questions. | 11-AUG-2021 | 1273180 |
| 11-AUG-2021 | Y | | Amendment # 44. This amendment was skipped by the Applicant. | 11-AUG-2021 | 1273179 |
| 12-AUG-2021 | Y | | Amendment # 45. Response to August 9. 2021, clinical IR RE sequencing data. | 12-AUG-2021 | 1278583 |
| 13-AUG-2021 | Y | | Amendment # 46. Response to August 9, 2021 IR RE Carton and Container labeling comments. | 13-AUG-2021 | 1284081 |
| 13-AUG-2021 | Y | | Amendment # 47. Response to DMPQ¿s August 11, 2021, diluent IR and amended response to Theresa Finn¿s August 5, 2021, IR regarding diluent. | 13-AUG-2021 | 1284082 |
| 13-AUG-2021 | Y | | Amendment # 48. Response to DBSQC¿s August 6, 2021, three questions RE measurement of (b) (4) using (b) (4) (b) (4) procedures. | 13-AUG-2021 | 1284088 |
| 16-AUG-2021 | Y | | Amendment # 49. Response to 3rd set of PI labeling comments that were sent on August 13, 2021. | 16-AUG-2021 | 1310580 |
| 16-AUG-2021 | Y | | Amendment # 50. Response to DBSQC¿s August 13, 2021, IR RE LRP and testing. | 16-AUG-2021 | 1310586 |
| 16-AUG-2021 | Y | | Amendment # 51. Response to August 13, 2021, IR RE Safety-related Postmarketing Requirement/Postmarketing Commitment studies. | 16-AUG-2021 | 1310587 |
| 16-AUG-2021 | Y | | Amendment # 52. Response to three clinical questions dated August 13, 2021, plus an additional clinical question dated August 13, 2021 (four total clinical questions dated August 13, 2021). | 16-AUG-2021 | 1310589 |
| 17-AUG-2021 | Y | | Amendment # 53. Response to August 16, 2021 IR RE Carton and Container labeling comments. | 17-AUG-2021 | 1318912 |
| 17-AUG-2021 | Y | | Amendment # 54. Response to follow-up to August 13, 2021, (b) (4) IR and August 16, 2021, teleconference on this subject containing a commitment to implement (b) (4) method on (b) (4) . | 17-AUG-2021 | 1320863 |
| 17-AUG-2021 | Y | | Amendment # 55. Response to Xiao Wang¿s August 16, 2021, IR to please submit the same CMC stability information that was submitted to EUA 27034.260 to your BLA STN 125742 .0. | 17-AUG-2021 | 1320989 |
| 17-AUG-2021 | Y | | Amendment # 56. Response to DMPQ¿s August 16, 2021, IR to (b) (4) (b) (4) . | 17-AUG-2021 | 1321046 |
| 17-AUG-2021 | Y | | Amendment # 57. Response to DMPQ¿s 7 facility questions dated August 13, 2021. | 17-AUG-2021 | 1321051 |
| 18-AUG-2021 | Y | | Amendment # 58. Response to August 17, 2021, 4th set of PI labeling comments. | 18-AUG-2021 | 1329921 |
| 18-AUG-2021 | Y | | Amendment # 59. Response to August 17, 2021, follow up IR RE PMR & PMC's commitments that were received in amendment 51 dated August 16, 2021. | 18-AUG-2021 | 1329922 |
| 18-AUG-2021 | Y | | Amendment # 60. Updated response to FDA form 483 for the Andover site based off of teleconference with CBER on August 17, 2021. | 18-AUG-2021 | 1331100 |
| 19-AUG-2021 | Y | | Amendment # 61. Responses to DVP¿s August 17, 2021, two questions regarding shelf life and date of manufacture. | 19-AUG-2021 | 1337760 |
| 19-AUG-2021 | Y | | Amendment # 62. Responses to DVP¿s August 17, 2021, two questions regarding the drug substance. | 19-AUG-2021 | 1337762 |
| 19-AUG-2021 | Y | | Amendment # 63. Responses to the third set of comments and questions on the carton and container labels. | 19-AUG-2021 | 1338337 |
| 19-AUG-2021 | Y | | Amendment # 64. Response to August 18, 2021, IR RE Identification of BLA-compliant lots and Letter to HCP. | 19-AUG-2021 | 1338338 |
| 19-AUG-2021 | Y | | Amendment # 65. Responses to DBSQC¿s August 18, 2021, IR. | 19-AUG-2021 | 1338341 |

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Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

| Date | Elec | Post | Description | FDA Recd Date | Login ID |
|---|---|---|---|---|---|
| 19-AUG-2021 | Y | | Amendment # 66. Response to August 18, 2021, 5th set of PI labeling comments. | 19-AUG-2021 | 1338872 |
| 19-AUG-2021 | Y | | Amendment # 67. Response August 19, 2021, IR RE PMR¿s and PMC¿s that were submitted in amendment 51. | 19-AUG-2021 | 1339769 |
| 20-AUG-2021 | Y | | Amendment # 68. Response to August 19, 2021, 6th set of PI labeling comments. | 20-AUG-2021 | 1341754 |
| 20-AUG-2021 | Y | | Amendment # 69. Additional Response to August 19, 2021, IR RE PMR¿s and PMC¿s that were submitted in amendment 51. | 20-AUG-2021 | 1341755 |
| 20-AUG-2021 | Y | | Amendment # 70. Letter of authorization for a new U.S. agent. This amendment was not in response to an information request. | 20-AUG-2021 | 1342120 |
| 20-AUG-2021 | Y | | Amendment # 71. Response to August 20, 2021, 7th set of PI comments and shell table. | 20-AUG-2021 | 1344590 |
| 20-AUG-2021 | Y | | Amendment # 72. Response to August 20, 2021, clinical IR regarding the shell table. | 20-AUG-2021 | 1344591 |
| 20-AUG-2021 | Y | | Amendment # 73. Response to August 20, 2021, CBER comments regarding label for identification of BLA lots and Dear HCP Letter | 20-AUG-2021 | 1344771 |
| 21-AUG-2021 | Y | | Amendment # 74. Response to August 21, 2021, 8th set of comments on the PI. | 23-AUG-2021 | 1344786 |
| 21-AUG-2021 | Y | | Amendment # 75. Response to August 21, 2021, IR RE PMR¿s and PMC¿s and final study protocol date for study C4591007 | 23-AUG-2021 | 1344787 |
| 21-AUG-2021 | Y | | Amendment # 76. Response to August 21, 2021, IR RE regarding identification of BLA lots/Dear HCP Letter. | 23-AUG-2021 | 1344788 |
| 23-AUG-2021 | Y | | Amendment # 77. Final PI (when compared to the PI received in STN 125.0.74 it was the same EXCEPT Pfizer¿s version number at the very end of the PI was changed from LAB-1448-.9 to LAB-1448-1.0). | 23-AUG-2021 | 1346819 |
| 24-AUG-2021 | Y | | Amendment # 78. Final PI which has been revised to include the license number | 24-AUG-2021 | 1350971 |
| 07-MAY-2023 | Y | | Amendment # 20. Response to July 13, 2021 OBE IR to add myocarditis and pericarditis to the PVP. | 29-JUL-2021 | 1230081 |
| 07-JUN-2023 | Y | | Amendment # 21. Response to July 16, 2021 DBSQC IR regarding (b) (4) (b) (4) test methods. | 30-JUL-2021 | 1232318 |
| 07-JUN-2023 | Y | | Amendment # 23. Response to July 26, 2021 clinical IR regarding the disposition of participants in safety populations who experienced pregnancy. | 30-JUL-2021 | 1235714 |