BLA 125742/0 COMIRNATY: Documentation Review Memo

Product Information: **COMIRNATY**
Indication and Use: **Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.**

Communications (IRs) from CBER:

IR #	Request Date	CBER Rep(s)	Request	CBER Requester for Information	BLA Amendment Response
1	5/18/21	Mike Smith	Three clinical questions regarding the datasets.	Clinical team and Lei Huang	STN 125742/0.3
2	5/20/21	Mike Smith	Four facilities questions and a request for a t-con on May 25 or 26, 2021, to discuss production schedules and (b) (4) (b) (4) for the Puurs, Belgium site.	Iryna Zubkova	STN 125742/0.4
3	6/8/2021	Mike Smith	Three clinical questions regarding datasets and the PI.	Clinical team	STN 125742/0.6
4	6/9/2021	Mike Smith	Clinical IR requesting dates for PREA deferred studies.	Clinical team	STN 125742/0.7
5	6/25/2021	Mike Smith	DBSQC IR regarding the lot release protocol (LRP) template and samples & reagents.	Marie Anderson	STN 125742/0.10
6	6/25/2021	Mike Smith	Clinical IR regarding the document titled "bnt162-01-interim3-report-body."	Clinical team	STN 127742/0.9
7	6/29/2021	Mike Smith	Clinical IR RE latest date of randomization for participants included in the reactogenicity subset for Study C4591001.	Clinical team	STN 127742/0.8
8	7/2/2021	Ram Naik	18 question from DVP on product related issues and categorical exclusion for an environmental assessment.	Xiao Wang	STN 127742/0.19
9	7/6/2021	Mike Smith	Clinical IR RE the document titled "c4591001-interim-mth6-report-body.pdf."	Clinical team	STN 127742/0.12
10	7/9/2021	Mike Smith	IR RE the validation of the RNA Integrity by capillary gel electrophoresis method.	DBSQC and DVP	STN 125742/0.16
11	7/13/2021	Mike Smith	OBE IR to add myocarditis and pericarditis to the PVP and submit to the BLA by July 19, 2021.	Deb Thompson	STN 125742/0.20
12	7/13/2021	Ram Naik	DVP IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative.	Xiao Wang	STN 125742/0.11
13	7/15/2021	Mike Smith	Clinical IR RE study C4591007 to provide updated goal dates for final protocol submission.	Clinical team	STN 125742/0.15

14	7/15/2021	Mike Smith	Updated advice to submit PVP to BLA by July 29, 2021.	Deb Thompson	STN 125742/0.20
15	7/16/2021	Laura Gottschalk	DBSQC IR regarding lot release protocol template and drug substance handling instructions.	Marie Anderson	STN 125742/0.14
16	7/16/2021	Laura Gottschalk	DBSQC IR regarding (b) (4) sterility and endotoxin test methods.	Karla Garcia	STN 125742/0.21
17	7/20/2021	Ram Naik	Clinical IR for a revised pediatric plan to include study C4591007 for children 6 months to 11 years of age and proposal for another study to enroll infants <6 months of age.	Clinical team	STN 125742/0.15
18	7/22/2021	Laura Gottschalk	Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments. (Pfizer informed us that shell tables will be provided by Aug 13. On July 26 we told them to submit the shell tables ASAP.)	Clinical team, Lei Huang and Ye Yang	STN 125742/0.17 STN 125742/0.18 STN 125742/0.28 STN 125742/0.32 STN 125742/0.37
19	7/26/2021	Laura Gottschalk	Clinical IR regarding the disposition of participants in safety populations who experienced pregnancy.	Clinical team	STN 125742/0.23
20	7/26/2021	Laura Gottschalk	DMPQ IR regarding manufacturing and equipment. (Remaining response to be submitted week of Aug 2.)	Laura Fontan	STN 125742/0.24 STN 125742/0.29
21	7/27/2021	Mike Smith	Two Clinical IR's RE vaccine effectiveness.	Clinical team	STN 125742/0.22
22	7/27/2021	Mike Smith	Third clinical IR RE vaccine effectiveness.	Clinical team	STN 125742/0.22
23	7/28/2021	Ram Naik	First set of labeling comments regarding the PI.	Clinical team and RPM labeling memo	STN 125742/0.27
24	7/28/2021	Ram Naik	OBE IR regarding postmarketing safety study(ies)	Clinical team and Yun Lu	STN 125742/0.30 & STN 125742/0.42
25	7/29/2021	Laura Gottschalk	Clinical IR regarding safety analysis for two age groups.	Clinical team	STN 125742/0.26
26	8/2/2021	Mike Smith	DVP and stats questions regarding the Validation Report VR-MVR-10077.	Xiao Wang and Xinyu Tang	STN 125742/0.31
27	8/2/2021	Mike Smith	Five questions regarding validation of assay methods and lot release.	DBSQC and Xiao Wang	STN 125742/0.35
28	8/3/2021	Mike Smith	Six CMC-related questions.	Xiao Wang	STN 125742/0.33
29	8/3/2021	Mike Smith	Two clinical/stats questions regarding July 26, 2021, submission and SAS program.	Lei Huang and Clinical team	STN 125742/0.32

30	8/4/2021	Mike Smith	Two questions regarding the potency assay for determination of in vitro expression (IVE) by flow cytometry.	Xinyu Tang and Xiao Wang	STN 125742/0.34
31	8/4/2021	Mike Smith	F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021.	Marie Anderson	STN 125742/0.40
32	8/4/2021	Mike Smith	Secondary F/U IR with attachment RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021.	Marie Anderson	STN 125742/0.40
33	8/5/2021	Mike Smith	11 facilities questions.	Kathy Jones	STN 125742/0.43
34	8/5/2021	Mike Smith	Four questions regarding the diluent.	RPM labeling memo	STN 125549/0.36
35	8/5/2021	Mike Smith	Second round of PI labeling comments.	Clinical and RPM labeling memo	STN 125549/0.38
36	8/6/2021	Mike Smith	Two questions from DVP regarding two drug product (DP) documents.	Xiao Wang	STN 125742/0.39
37	8/6/2021	Mike Smith	Three DBSQC questions RE measurement of endotoxins using the (b) (4) LAL procedures.	DBSQC	STN 125742/0.48
38	8/9/2021	Mike Smith	Clinical IR RE sequencing data.	Clinical team	STN 125742/0.45
39	8/9/2021	Mike Smith	Carton and Container labeling comments.	Daphne Stewart and RPM labeling memo	STN 125742/0.46
40	8/10/2021	Ram Naik	Second OBE IR regarding safety-related postmarketing studies.	Yun Lu	STN 125742/0.42
41	8/10/2021	Mike Smith	One testing related question from DBSQC.	Hsiaoling Wang	STN 125742/0.41
42	8/11/2021	Mike Smith	One diluent IR from DMPQ.	DMPQ	STN 125742/0.47
43	8/13/2021	Mike Smith	Three clinical questions.	Clinical team	STN 125742/0.52
44	8/13/2021	Mike Smith	DBSQC IR RE LRP and testing.	DBSQC	STN 125742/0.50
45	8/13/2021	Mike Smith	Pfizer asked a clarification question regarding one of the three clinical questions for August 13, 2021, and this IR was a response to the clarification question.	Clinical team	STN 125742/0.52
46	8/13/2021	Mike Smith	7 facility questions from the DMPQ team.	DMPQ	STN 125742/0.57
47	8/13/2021	Mike Smith	3rd set of PI labeling comments.	Clinical team and RPM labeling memo	STN 125742/0.49
48	8/13/2021	Mike Smith	One clinical question.	Clinical team	STN 125742/0.52

49	8/13/2021	Ram Naik	Safety-related Postmarketing Requirement/Postmarketing Commitment studies	Clinical team, and Yun Lu	STN 125742/0.51
50	8/16/2021	Mike Smith	DMPQ IR RE diluent suppliers and removing Pfizer Healthcare India Pvt. Ltd. as a supplier of diluent for the BLA.	DMPQ	STN 125742/0.56
51	8/16/2021	Mike Smith	Second set of comments and questions on the carton and container labels.	Daphne Stewart and RPM labeling memo	STN 125742/0.53
52	8/16/2021	Ram Naik	Request to submit the same CMC stability information that was submitted to EUA 27034.260 to the BLA STN 125742/0 so that we can consider a 9-month shelf-life for the licensed product.	Xiao Wang	STN 125742/0.55
53	8/17/2021	Mike Smith	Two questions regarding the drug substance.	Xiao Wang	STN 125742/0.62
54	8/17/2021	Mike Smith	4th set of PI labeling comments	Clinical team and RPM labeling memo	STN 125742/0.58
55	8/17/2021	Mike Smith	Two questions for DVP regarding shelf life and date of manufacture.	Xiao Wang	STN 125742/0.61
56	8/17/2021	Ram Naik	Follow up IR RE PMR & PMC studies that were received in amendment 51 dated August 16, 2021.	Clinical team	STN 125742/0.59
57	8/18/2021	Mike Smith	Pfizer asked clarification question on DVP's two questions from August 17, 2021, on DS. This e-mail was guidance in response to their clarification questions.	Xiao Wang	STN 125742/0.62
58	8/18/2021	Mike Smith	Two DBSQC questions on amendments 54 and 50 RE endotoxin testing and specific parameters/instructions for (b) (4) in the CGE integrity test method.	DBSQC	STN 125742/0.65
59	8/18/2021	Mike Smith	DVP follow-up response to Pfizer's August 18, 2021, clarification questions regarding DVP's August 17, 2021, IR on shelf life and date of manufacture.	Xiao Wang	STN 125742/0.61
60	8/18/2021	Mike Smith	5th set of PI labeling comments.	Clinical team and RPM labeling memo	STN 125742/0.66
61	8/18/2021	Laura Gottschalk	Third set of comments and questions on the carton and container labels.	Daphne Stewart and RPM labeling memo	STN 125742/0.63

62	8/18/2021	Ram Naik	IR RE identification of BLA-compliant lots and Letter to HCP	RPM labeling memo/SBRA	STN 125742/0.64
63	8/19/2021	Mike Smith	IR RE PMR's and PMC's that were submitted in amendment 51.	Clinical team	STN 125742/0.67 STN 125742/0.69
64	8/19/2021	Laura Gottschalk	6th set of PI labeling comments. (Response requested by COB 8/19/21.)	Clinical team and RPM labeling memo	STN 125742/0.68
65	8/20/2021	Laura Gottschalk	7th set of PI comments and shell table.	Clinical team and RPM labeling memo	STN 125742/0.71 STN 125742/0.72
66	8/20/2021	Ram Naik	CBER comments regarding identification of BLA lots/Dear HCP Letter	RPM labeling memo/SBRA	STN 125742/0.73
67	8/21/2021	Mike Smith	IR RE PMR's and PMC's to be submitted in one amendment and revised final protocol submission date for PMC study C4591007.	Clinical team	STN 125742/0.75
68	8/21/2021	Laura Gottschalk	8th set of PI labeling comments.	Clinical team and RPM labeling memo	STN 125742/0.74
69	8/21/2021	Ram Naik	Second set of comments regarding identification of BLA lots/Dear HCP Letter	RPM labeling memo/SBRA	STN 125742/0.76

Amendments:

Date/STN	Summary	Reviewed by and date reviewed:
5/18/2021 125742/0.1	Second roll and final piece of the BLA, the review clock has started. **This amendment was not submitted in response to an IR.**	Clinical team (September 2, 2021) Ye Yang (August 19, 2021) Xiao Wang (August 21, 2021) Deborah Thompson (August 6, 2021) Marie Anderson (August 18, 2021) Oluchi Elekwachi (August 6, 2021) DMPQ team (August 22, 2021)
5/19/2021 125742/0.2	Request for Proprietary Name Review. **This amendment was not submitted in response to an IR.**	Oluchi Elekwachi (July 2, 2021) Clinical team (September 2, 2021)
5/19/2021 125742/0.3	Response to May 18, 2021, clinical IR RE three dataset questions.	Clinical team (September 2, 2021) Lei Huang (August 19, 2021) Ye Yang (August 19, 2021)
5/24/2021 125742/0.4	Response to May 20, 2021, DMPQ IR RE four facilities questions and a request for a t-con on May 25 or 26, 2021, to discuss production schedules and (b) (4) for the Puurs, Belgium site.	DMPQ team (August 22, 2021)
6/7/2021 125742/0.5	COVID-19 case strain sequencing data. **This amendment was not submitted in response to an IR.**	Clinical team (September 2, 2021)
6/16/2021 125742/0.6	Response to June 8, 2021, clinical IR on three clinical questions regarding datasets and the PI.	Clinical team (September 2, 2021)
6/17/2021 125742/0.7	Response to June 9, 2021, clinical IR requesting dates for PREA deferred studies.	Clinical team (September 2, 2021)
7/2/2021 125742/0.8	Response to June 29, 2021, clinical IR RE latest date of randomization for participants included in the reactogenicity subset for Study C4591001.	Clinical team (September 2, 2021)
7/2/2021 125742/0.9	Response to June 25, 2021, clinical IR regarding IR regarding the document titled "bnt162-01-interim3-report-body."	Clinical team (September 2, 2021)
7/9/2021 125742/0.10	Response to June 25, 2021, DBSQC IR regarding the lot release protocol (LRP) template and samples & reagents.	Marie Anderson (August 18, 2021) Xiao Wang (August 21, 2021)
7/15/2021 125742/0.11	Response to July 13, 2021, DVP IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative.	Xiao Wang (August 21, 2021)
07/16/2021 125742/0.12	Response to July 6, 2021, clinical IR regarding IR regarding the document titled "c4591001-interim-mth6-report-body.pdf."	Clinical team (September 2, 2021)

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Date/STN	Summary	Reviewed by and date reviewed:
07/19/2021 125742/0.13	The applicant waives their rights to the mid- and late-cycle review meetings for BLA 125742. **This amendment was not submitted in response to an IR.**	N/A
07/20/2021 125742/0.14	Response to July 16, 2021, DBSQC IR regarding lot release protocol template and drug substance handling instructions.	Marie Anderson (August 18, 2021)
7/23/2021 125742/0.15	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.	Clinical team (September 2, 2021)
7/23/2021 125742/0.16	Response to July 9, 2021, IR RE the validation of the RNA Integrity by capillary gel electrophoresis method.	DBSQC team (August 21, 2021) Xiao Wang (August 21, 2021)
7/26/2021 125742/0.17	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.	Clinical team (September 2, 2021) Lei Huang (August 19, 2021)
7/28/2021 125742/0.18	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.	Clinical team (September 2, 2021) Lei Huang (August 19, 2021)
7/28/2021 125742/0.19	Response to July 2, 2021, DVP IR regarding 18 question on product related issues and categorical exclusion for an environmental assessment.	Xiao Wang (August 21, 2021) Xinyu Tang (August 18, 2021) DMPQ team (August 22, 2021)
7/29/2021 125742/0.20	Response to July 13, 2021, OBE IR to add myocarditis and pericarditis to the PVP.	Deborah Thompson (August 6, 2021) Yun Lu (August 22, 2021)
7/30/2021 125742/0.21	Response to July 16, 2021, DBSQC IR regarding (b) (4) sterility and endotoxin test methods.	DBSQC team (August 21, 2021)
07/30/2021 125742/0.22	Response to July 27, 2021, clinical three questions RE vaccine effectiveness.	Clinical team (September 2, 2021)
07/30/2021 125742/0.23	Response to July 26, 2021, clinical IR regarding the disposition of participants in safety populations who experienced pregnancy.	Clinical team (September 2, 2021)
07/30/2021 125742/0.24	Response to July 26, 2021, DMPQ IR regarding manufacturing and equipment.	DMPQ team (August 22, 2021)

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Date/STN	Summary	Reviewed by and date reviewed:
8/2/2021 125742/0.25	Response to the observations contained in the FDA form 483 that was issued for the pre-approval inspection of the Pfizer Andover facility. **This amendment was not submitted in response to an IR.**	N/A
8/2/2021 STN 125742/0.26	Response to July 29, 2021, clinical IR regarding safety analysis for two age groups.	Clinical team (September 2, 2021) Ye Yang (August 19, 2021)
8/2/2021 125742/0.27	Response to July 28, 2021, first set of labeling comments regarding the PI.	Clinical team (September 2, 2021) Xiao Wang (August 21, 2021) Lei Huang (August 19, 2021) Oluchi Elekwachi (August 6, 2021) RPM labeling memo (September 1, 2021)
8/2/2021 125742/0.28	Response to comment 5b of July 22, 2021, clinical-statistical IR	Clinical team (September 2, 2021) Lei Huang (August 19, 2021)
8/3/2021 125742/0.29	Follow-up response (remaining supporting documents to response 10) to July 26, 2021, DMPQ IR regarding manufacturing and equipment.	DMPQ team (August 22, 2021)
8/3/2021 125742/0.30	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	Yun Lu (August 22, 2021) Clinical team (September 2, 2021)
8/5/2021 125742/0.31	Response to DVP and stats August 2, 2021, questions regarding the Validation Report VR-MVR-10077.	Xiao Wang (August 21, 2021)
8/5/2021 125742/0.32	Response to clinical and stats IR's from July 22, 2021, and August 3, 2021, regarding shell tables and two additional clinical/stats questions regarding July 26, 2021, submission and SAS program.	Clinical team (September 2, 2021) Lei Huang (August 19, 2021)
8/6/2021 125742/0.33	Responses to DVP's six CMC-related questions from August 3, 2021.	Xiao Wang (August 21, 2021)
8/6/2021 125742/0.34	Responses to August 4, 2021, IR RE two questions regarding the potency assay for determination of in vitro expression (IVE) by flow cytometry.	Xinyu Tang (August 18, 2021) Xiao Wang (August 21, 2021)
8/9/2021 125742/0.35	Response to DBSQC and Xiao Wang's August 2, 2021, questions regarding validation of assay methods and lot release.	DBSQC team (August 20, 2021) Xiao Wang (August 21, 2021)
8/9/2021 125742/0.36	Response to four questions regarding the diluent dated August 5, 2021.	Xiao Wang (August 21, 2021) RPM labeling Memo (September 1, 2021)

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Date/STN	Summary	Reviewed by and date reviewed:
8/9/2021 125742/0.37	Response to July 22, 2021, Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments.	Clinical team (September 2, 2021) Ye Yang (August 19, 2021)
8/9/2021 125742/0.38	Revised PI labeling in response to August 5, 2021, second round of labeling comments.	Clinical team (September 2, 2021) Lei Huang (August 19, 2021) RPM labeling memo (September 1, 2021)
8/10/2021 125742/0.39	Response to Xiao Wang's August 6, 2021, questions regarding two drug product (DP) documents.	Xiao Wang (August 21, 2021) DMPQ team (August 22, 2021)
8/11/2021 125742/0.40	Response to August 4, 2021, F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021.	Marie Anderson (August 18, 2021)
8/11/2021 125742/0.41	Response to one testing related question from DBSQC on August 10, 2021.	Hsiaoling Wang (August 30, 2021)
8/11/2021 125742/0.42	Response to August 10, 2021, second OBE IR regarding safety-related postmarketing studies.	Yun Lu (August 22, 2021)
8/11/2021 125742/0.43	Responses to DMPQ's August 5, 2021 11 facilities questions.	DMPQ team (August 22, 2021)
125742/0.44	This amendment was skipped.	N/A
8/12/2021 125742/0.45	Response to August 9, 2021, clinical IR RE sequencing data.	Clinical team (September 2, 2021)
8/13/2021 125742/0.46	Response to August 9, 2021 IR RE Carton and Container labeling. comments.	Daphne Stewart (August 20, 2021) RPM labeling Memo (September 1, 2021)
8/13/2021 125742/0.47	Response to DMPQ's August 11, 2021, diluent IR and amended response to August 5, 2021, IR regarding diluent.	DMPQ team (August 22, 2021) Xiao Wang (August 21, 2021)
8/13/2021 125742/0.48	Response to DBSQC's August 6, 2021, three questions RE measurement of endotoxins using the (b) (4) LAL procedures.	DBSQC team (August 21, 2021)
8/16/2021 125742/0.49	Response to 3rd set of PI labeling comments that were sent on August 13, 2021.	Clinical team (September 2, 2021) RPM labeling memo (September 1, 2021)
8/16/2021 125742/0.50	Response to DBSQC's August 13, 2021, IR RE LRP and testing.	Marie Anderson (August 18, 2021) DBSQC team (August 21, 2021)
8/16/2021 125742/0.51	Response to August 13, 2021, IR RE Safety-related Postmarketing Requirement/Postmarketing Commitment studies.	Clinical team (September 2, 2021) Yun Lu (August 22, 2021)

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Date/STN	Summary	Reviewed by and date reviewed:
8/16/2021 125742/0.52	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).	Clinical team (September 2, 2021)
8/17/2021 125742/0.53	Response to August 16, 2021 IR RE Carton and Container labeling comments.	Daphne Stewart (August 20, 2021) RPM labeling Memo (September 1, 2021)
8/17/2021 125742/0.54	Response to follow-up to August 13, 2021, endotoxin IR and August 16, 2021, teleconference on this subject containing an agreement to implement an (b) (4) endotoxin method on (b) (4) DP.	DBSQC team (August 21, 2021)
8/17/2021 125742/0.55	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 this BLA STN 125742 .0.	Xiao Wang (August 21, 2021) DMPQ team (August 22, 2021)
8/17/2021 125742/0.56	Response to DMPQ's August 16, 2021, IR to remove Pfizer Healthcare India Pvt. Ltd. as a supplier of diluent for the BLA.	DMPQ team (August 22, 2021)
8/17/2021 125742/0.57	Response to DMPQ's 7 facility questions dated August 13, 2021.	DMPQ team (August 22, 2021)
8/18/2021 125742/0.58	Response to August 17, 2021, 4th set of PI labeling comments.	Clinical team (September 2, 2021) RPM labeling memo (September 1, 2021)
8/18/2021 125742/0.59	Response to August 17, 2021, follow up IR RE PMR & PMC's that were received in amendment 51 dated August 16, 2021.	Clinical team (September 2, 2021)
8/18/2021 125742/0.60	Updated response to FDA form 483 for the Andover site based off of teleconference with CBER on August 17, 2021.	DMPQ team (August 22, 2021, Andover Inspection Closeout Memorandum)
8/19/2021 125742/0.61	Responses to DVP's August 17, 2021, two questions regarding expiry dating period and date of manufacture.	Xiao Wang (August 21, 2021)
8/19/2021 125742/0.62	Responses to DVP's August 17, 2021, two questions regarding the drug substance.	Xiao Wang (August 21, 2021) DMPQ team (August 22, 2021)
8/19/2021 125742/0.63	Responses to August 18, 2021, third set of comments and questions on the carton and container labels.	Daphne Stewart (August 20, 2021) RPM labeling Memo (September 1, 2021)
8/19/2021 125742/0.64	Response to August 18, 2021, IR RE identification of BLA-compliant lots/Letter to HCP.	RPM labeling memo (September 1, 2021) SBRA (August 22, 2021)
8/19/2021 125742/0.65	Responses to DBSQC's August 18, 2021, IR.	DBSQC team (August 21, 2021)
8/19/2021 125742/0.66	Response to August 18, 2021, 5th set of PI labeling comments.	Clinical team (September 2, 2021) RPM labeling memo (September 1, 2021)

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Date/STN	Summary	Reviewed by and date reviewed:
8/19/2021 125742/0.67	Response to August 19, 2021, IR RE PMR's and PMC's that were submitted in amendment 51.	Clinical team (September 2, 2021)
8/20/2021 125742/0.68	Response to August 19, 2021, 6th set of PI labeling comments.	Clinical team (August 23, 2021) RPM labeling memo (September 1, 2021)
8/20/2021 125742/0.69	Additional Response to August 19, 2021, IR RE PMR's and PMC's that were submitted in amendment 51.	Clinical team (September 2, 2021)
8/20/2021 125742/0.70	Letter of authorization for a new Point of contact in the U.S. agent. **This amendment was not in response to an information request.**	David Dickerson (no memo required)
8/20/2021 125742/0.71	Response to August 20, 2021, 7th set of comments on the PI.	Clinical team (September 2, 2021) RPM labeling memo (September 1, 2021)
8/20/2021 125742/0.72	Response to August 20, 2021, IR regarding an additional shell table.	Clinical team (September 2, 2021)
8/20/2021 125742.0.73	Response to August 20, 2021, CBER comments regarding identification of BLA lots/Dear HCP Letter.	RPM labeling memo (September 1, 2021) SBRA (August 22, 2021)
8/21/2021 125742/0.74	Response to August 21, 2021, 8th set of comments on the PI.	Clinical team (September 2, 2021) RPM labeling memo (September 1, 2021)
8/21/2021 125742/0.75	Response to August 21, 2021, IR RE PMR's and PMC's and final study protocol date for study C4591007	Clinical team (September 2, 2021)
8/21/2021 125742/0.76	Response to August 21, 2021, IR RE regarding identification of BLA lots/Dear HCP Letter.	RPM labeling memo (September 1, 2021) SBRA (August 22, 2021)
8/23/2021 125742/0.77	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).	Received after the BLA was approved but sent to clinical team, APLB reviewer and RPMs. RPM labeling memo (September 1, 2021)
8/24/2021 125742/0.78	Final PI which has been revised to include the license number	Received after the BLA was approved but sent to APLB reviewer and RPMs. RPM labeling memo (September 1, 2021) (Note: this last version of the PI was also sent to OCOD to post to the web in place of the previous version that had been sent on the day of approval.)