

STN 125742/45: BioNTech Manufacturing GmbH's COMIRNATY sBLA Documentation Review Memo

Michael J. Smith - Digitally signed by Michael J. Smith -S4
Date: 2022.08.02 13:12:08 -04'00'

BLA 125742/45: Documentation Review Memo

Elizabeth M. Sutkowski -S Digitally signed by Elizabeth M. Sutkowski -S
Date: 2022.08.24 21:28:02 -04'00'

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 12 years of age and older.

Communications (IRs) from CBER:

IR #	Request Date	CBER Rep(s)	Request	CBER Requester for Information	BLA Amendment Response
1	1/19/22	Mike Smith	Three questions RE datasets	Brenda Baldwin and Susan Wollersheim	STN 125742.45.2
2	1/25/22	Mike Smith	IR RE EA/CE and FDA form 356	Mike Smith	STN 125742.45.1
3	2/23/22	Mike Smith	OBE IR RE two questions on Cumulative Analysis of Post-Authorization Adverse Event Reports	Deb Thompson	STN 125742.45.3
4	3/7/22	Mike Smith	Two Clinical-statistical comments regarding updated immunobridging analyses and solicited adverse reaction frequencies.	Susan Wollersheim and Ye Yang	STN 125742.45.4
5	3/8/22	Mike Smith	Follow-up response to Pfizer's March 8, 2022, clarification question to the review team's March 7, 2022, IR.	Susan Wollersheim and Ye Yang	STN 125742.45.4
6	3/14/22	Mike Smith	Statistical F/U IR RE Pfizer's response in STN 125742.45.4 to our 3/7/22 clinical and statistical questions.	Ye Yang	STN 125742.45.7
7	4/8/2022	Ram Naik	IR RE Comirnaty sBLA to extend the indication to adolescents 12 through 15 years of age - CBER comment regarding Tris/Sucrose formulation	Xiao Wang	STN 125742.12
8	4/20/2022	Mike Smith	Request to update the PVP to include both Tris/Sucrose and PBS/Sucrose formulations.	Deb Thompson	STN 125742.45.9
9	4/20/2022	Laura Gottschalk	First set of labeling comments on PI	Susan Wollersheim	STN 125742.45.8
10	4/22/2022	Mike Smith	IR RE request for a revised study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)	Deb Thompson	STN 125742.45.10
11	4/26/2022	Mike Smith	Follow-up communication RE 4/22/22 IR from OBE.	Deb Thompson	STN 125742.10

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12	5/4/2022	Mike Smith	IR RE placebo recipient information contained in the PI	Susan Wollersheim	STN 125742.45.11
13	5/10/2022	Mike Smith	Second set of PI labeling comments.	Susan Wollersheim	STN 125742.45.12
14	6/29/2022	Mike Smith	Third set of PI labeling comments.	Susan Wollersheim	STN 125742.45.13
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Amendments:

Date/STN	Summary	Reviewed by and date of final review:
1/28/2022 STN 125742.45.1	Responses to 1/25/22 IR RE EA/CE and FDA form 356	Mike Smith and Laura Gottschalk Xiao Wang (5/2/2022)
2/2/2022 STN 125742.45.2	Response to 1/19/22 three questions RE datasets	Brenda Baldwin (4/22/2022), Ye Yang (4/11/2022) and Susan Wollersheim (7/8/2022)
3/1/2022 STN 125742.45.3	Response to 2/23/22 OBE IR Cumulative Analysis of Post- Authorization Adverse Event Reports	Deb Thompson (5/6/2022)
3/11/2022 STN 125742.45.4	Response to 3/7/22 clinical-statistical comments regarding updated immunobridging analyses and solicited adverse reaction frequencies.	Susan Wollersheim (7/8/2022) and Ye Yang (4/11/2022)

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Date/STN	Summary	Reviewed by and date of final review:
3/15/2022 STN 125742.45.5	Request from Pfizer for comments on booster dose for adolescents 12 through 15 years of age in the same sBLA planned to apply for licensure of a booster dose for individuals 16 years of age and older as a single submission.	N/A
3/16/2022 STN 125742.45.6	Withdrawal of STN 125742.45.5	N/A
3/18/2022 STN 125742.45.7	Response to 3/14/22 Follow-up question regarding Pfizer’s response in STN 125742.45.4 to our 3/7/22 clinical and statistical questions.	Ye Yang (4/11/2022)
4/29/2022 STN 125742.45.8	Response to 4/20/22 first set of labeling comments on PI	Susan Wollersheim (7/8/2022) and RPM labeling memo (8/2/2022)
5/2/2022 STN 125742.45.9	Response to 4/20/22 request to update the PVP to include both Tris/Sucrose and PBS/Sucrose formulations.	Deb Thompson (5/6/2022)
5/4/2022 STN 125742.45.10	Response to 4/22/22 request to submit a revised study protocol for Study C4591022 - pregnancy registry study (postmarketing commitment (PMC) #10 as described in the STN 125742/0 approval letter)	Deb Thompson (5/6/2022)
5/9/2022 STN 125742.45.11	Response to 5/4/2022 IR RE placebo recipient information contained in the PI.	Susan Wollersheim (7/8/2022)
5/13/2022 STN 125742.45.12	Response to 5/10/22 second set of labeling comments on PI	Susan Wollersheim (7/8/2022) and RPM labeling memo (8/2/2022)
7/1/2022 STN 125742.45.13	Response to 6/29/22 third set of labeling comments on PI	Susan Wollersheim (7/8/2022) and RPM labeling memo (8/2/2022)