Pfizer-BioNTech COVID-19 Vaccine

Response to CBER 04 May 2022 Information Request Regarding Package Insert Information for Reported Nausea in Placebo Recipients 12-15 Years of Age

09 May 2022

LIST OF ABBREVIATIONS

CBER	Center for Biologics Evaluation and Research
COVID-19	Coronavirus Disease 2019
FDA	(US) Food and Drug Administration
EUA	Emergency Use Authorization
PI	package insert
sBLA	supplemental Biologics License Application
USPI	United States package insert

1. INTRODUCTION

Reference is made to the EUA for the Pfizer-BioNTech COVID-19 Vaccine granted on 10 May 2021 to expand use to individuals 12-15 years of age, and to the sBLA submitted on 16 December 2021 (STN12542.45), for the expansion of licensure to individuals 12-15 years of age.

Reference is also made to an email received from Mike Smith, Ph.D. (CBER) by Kathleen Collins (Pfizer) on 04 May 2022 regarding placebo recipient information contained in the PI that was submitted to STN12542.45, based on the dataset (02 September 2021 data cutoff) submitted in the referenced sBLA for the participants 12-15 years of age who received 2 doses of BNT162b2 30 µg.

CBER's requests are shown below in ***bold italics*** followed by Pfizer/BioNTech's responses.

2. COMMENTS AND REQUESTS

2.1. Request 1

The review team has the below information request regarding placebo recipient information contained in the Package Insert (PI) that was submitted to STN 125742.45 and they requested a response by Monday, May 9th.

Please confirm the number of placebo recipients who reported nausea from Dose 1 through 1 month after Dose 2, based on the September 2, 2021 data cutoff. There appears to be 2 placebo recipients who reported nausea from Dose 1 through 1 month post Dose 2, based on our analysis of the 6-mo ADAE dataset.

Response

The referenced PI cites 1 participant in the placebo group that reported nausea from Dose 1 to 1 month post Dose 2 based on the 13 March 2021 data cutoff date for the referenced 12-15 years EUA amendment.

Upon review of the dataset based on the 02 September 2021 cutoff, it was determined that the updates reported after the EUA snapshot would not impact the interpretation of the data included in the EUA submission. The additional AEs reported since the 13 March 2021 cutoff were summarized in the sBLA submission.

In the dataset based on the 02 September 2021 cutoff, an additional AE of nausea was reported in the placebo group (the AE occurred within 1 month post Dose 2 but was entered to the database after the EUA snapshot); thus, a total of 2 placebo recipients reported nausea from Dose 1 to 1 month post Dose 2.

The Sponsor will update the USPI to reflect the 2 participants in the placebo group that reported nausea from Dose 1 to 1 month post Dose 2, at the next round of FDA labeling comments.

Document Approval Record

Document Name:	COVID-19 Vaccine - Response to CBER on PI Nausea Data for Placebo_09 May 2022
Document Title:	COVID-19 Vaccine - Response to CBER on PI Nausea Data for Placebo_09 May 2022

Signed By:	Date(GMT)	Signing Capacity
Kitchin, Nicholas	09-May-2022 08:22:26	Final Approval