CONCURRENCE PAGE

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Application #: STN: BL 125742/8

Communication Name: Notification

Communication ID: WR LTR- OBE Safety Related

Drafted by: Christopher Okoye: 09/27/2021

Review/Concurrence History:
Craig Zinderman: 09/29/2021
Lori Austin-Hansberry: 09/29/2021

cc: CBER Electronic Repository

END OF CONCURRENCE PAGE

The letter begins on the next page

Our STN: BL 125742/8 September 29, 2021

BioNTech Manufacturing GmbH
Attention: Amit Patel
235 East 42nd Street
New York, New York 10017

Re: Request for Waiver under Title 21 Code of Federal Regulations 600.90(a)

Dear Amit Patel:

In the letter dated September 15, 2021, BioNTech Manufacturing GmbH requests an extension of the first reporting period for Lot Distribution Reporting (LDR) for COMIRNATY [COVID-19 mRNA Vaccine (nucleoside modified)], Biologics License Applications (BLA) 125742/0 from September 2021 to January 2022. BioNTech also requests to align the BLA LDR reporting requirement with quarterly reporting per the Emergency Use (EUA) as outlined in the re-authorization issued on August 23, 2021.

BioNTech requests a temporary waiver of four months to allow additional time to set up the required electronic systems needed for submission of LDR in SPL format. The additional time will allow for routine reporting in the appropriate format. BioNTech states the information needed to support both the BLA and EUA reporting requirements is similar and therefore alignment between the reporting period for the BLA and EUA is requested. The 1st EUA quarterly report was provided to FDA in July 2021. BioNTech proposes to submit the first BLA LDR with the January 2022 EUA report.

On June 10, 2014, FDA issued a final rule which, among other things, amended the requirements as to biological LDRs required under Title 21 of the Code of Federal Regulations 600.81 (21 CFR 600.81). Specifically, under this rule, applicants are required to submit LDRs to FDA in an electronic format that the Agency can process, review and archive (79 FR 33072). This reporting requirement was in effect as of June 10, 2015. Please note that the rule does not change the content of these reports[1].

Based upon our review, BioNTech request for extension of the first reporting period for Lot Distribution Reporting (LDR) for COMIRNATY [COVID-19 mRNA Vaccine (nucleoside modified)] is GRANTED. Therefore, as of the date of this letter and per 21 CFR 600.90 (b), the reporting interval of your first LDR will include the first 3 months following the initial approval of COMIRNATY and this first LDR will be submitted in

[1] See FDA Guidance for Industry: "Electronic Submission of Lot Distribution Reports, March 2015." FDA Guidance available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-lot-distribution-reports

January 2022, and thus, remain in compliance with the distribution reporting requirements per 21 CFR 600.81. Your request to waive the submission of monthly BLA LDR in lieu of submission of quarterly LDR to align with the EUA LDR reporting requirements is DENIED.

Also, please note that this letter in no way affects your other reporting responsibilities under our regulations, except as specifically outlined in this letter.

If you have any questions, please contact Lori Austin-Hansberry, Senior Regulatory Project Manager, at Lori.Austin-Hansberry@fda.hhs.gov.

Sincerely,

Craig E. Zinderman -S

Digitally signed by Craig E. Zinderman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300367569, cn=Craig E. Zinderman -S
Date: 2021.09.29 13:17:37 -04'00'

Craig Zinderman, MD, MPH
Associate Director for Medical Policy
Office of Biostatistics and Epidemiology
Center for Biologics
Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov