DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM FOR RECORD

To STN # 125742/0 August 20, 2021

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Subject CBER In-support Sterility and Bacterial Endotoxin Test (BET) Results for COVID-19 mRNA Vaccine, COMIRNATY

The DBSQC's Laboratory of Microbiology, *In-vivo* Testing and Standards tested three lots of COVID-19 mRNA Vaccine final drug product for sterility using the membrane filtration test method (TM: 000388, v10) and bacterial endotoxin using the (b) (4) test method (TM: 000575, v04), to support approval of STN 125742/0 submitted by BioNTech Manufacturing GmbH, in partnership with Pfizer, Inc. (Pfizer).

The sterility and bacterial endotoxin results obtained by CBER along with those of Pfizer are listed below:

Sterility and (b) (4) BET Results

Lot Number	CBER & Pfizer Sterility Test Results*1	BET Test Dilution	CBER % Spike Recovery	CBER Results*2 (EU/mL)	Pfizer's Results (EU/mL)	Proposed Specification (EU/mL)
FC3181	Passed	(b) (4)	(b) (4)			(b) (4)
FC3184	Passed	(b) (4)				(b) (4)
FD0809	Passed	(b) (4)				(b) (4)

*1 Sterility lot-release specification is No growth of bacteria and fungi
*2 (b) (4) Test Kit

CBER performed the compendial sterility test per TM 000388 to confirm Pfizer's (b) (4) (b) (4) sterility test results, as CBER does not have the (b) (4) sterility testing system in-house. No microorganism growth was observed in the lots tested by CBER using the compendial sterility test, confirming the test results obtained by Pfizer using the (b) (4) system. CBER's in-support sterility test results for all lots met the specification required to report the result as a pass.

The (b) (4) BET performed at CBER followed the firm's Standard Operating Procedure (SOP) TM-8914A and analytical method validation report (BET-102720-R0-HC Version 003), including a (b) (4) followed by sample dilution in (b) (4). A dilution of (b) (4) was used and these three test samples showed no inhibition or enhancement as the spike recoveries for the positive product control were 77-106% (acceptance criteria (b) (4) CBER's in- support test results indicate the bacterial endotoxin concentration met the specification of (b) (4) for all conformance lots.

In conclusion, the sterility and bacterial endotoxin results from tests performed by CBER are comparable to the values reported in Pfizer's Certificate of Analysis and were within the proposed specification.