Reference is made to Query Response #10 from FDA Information Request received 26 July 2021 received via email from Laura Gottschalk, OhD (CBER/OVRR):

"Please clarify if any drug substance direct product contact items (e.g., single-use system, tubing, gaskets, small parts) used in either (b) (4) are autoclave sterilized. If so, please provide the autoclave load validation summary report for the heat penetration studies. Ensure that the heat penetration information includes a detailed description of each autoclaved item (i.e., size and length of tubing, type of filter, size of container, wrapping in bag, etc.), thermocouple and biological indicator placement locations, cycle parameters used during validation and in normal production operations, validation acceptance criteria, results and any deviations."

On 30 July 2021 Pfizer provided a partial response to this query. Due to the file size of some of the attachments to Response #10, not all the supporting documents were able to be submitted under the initial. The remaining supporting documents below are now submitted to complete response #10:

(b) (4)