

As follow up from the teleconference with CBER on 16 August 2021 and recognizing CBER's previous request of 06 August 2021 to:

- identify a (b) (4) for testing DP within the (b) (4) (b) (4), and to
- provide a date by which results from the test using (b) (4) samples can be included of DP lot release.

### **Commitment to Implement (b) (4) Endotoxin Test Method**

Pfizer commits to implementing a new method that includes testing the (b) (4) sample for routine lot release testing of Drug Product by 06 December 2021. Implementation of the method would occur following method transfer and verification steps. A new routine test (b) (4) of the (b) (4) sample will be established based on the (b) (4) determined from the method verification study. (b) (4)