

WAIVER REQUEST – LOT DISTRIBUTION REPORTS

Per 21 CFR 600.81 a Lot Distribution Report (LDR) is to be provided in electronic format every six months or at times other than every 6 months as determined at the time of approval. For COMIRNATY, the LDR was requested monthly per the BLA approval issued on 23 August 2021. The purpose of this General Correspondence is to request an extension of the first reporting period from September 2021 to January 2022. A waiver is also requested to align the LDR reporting requirement with quarterly reporting per the Emergency Use Authorization (EUA) as outlined in the re-authorization issued on 23 August 2021. A January 2022 LDR report would align with the quarterly EUA report next due after the October 2021 report.

Justification for the Request

Due to the rapid approval of COMIRNATY, Pfizer/BioNTech request a temporary waiver of four months (from September 2021 to January 2022) to allow additional time needed to set up required electronic systems needed for submission of the LDR in SPL format. The monthly LDR reporting requirement requires specific electronic reporting format and license holder product distribution information. This information must be provided to a third-party contractor for conversion into the correct reporting format. As Pfizer and BioNTech have different inventory and quality systems to report lot distribution information, additional time is needed to enable routine reporting in the appropriate format.

In addition, some information under an LDR is also required to be reported under the EUA. The EUA states the following:

“Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.”

As information needed to support both the BLA and EUA reports is similar, it is expected that the same organizational groups will be needed to support both reports. As a result, alignment between the reporting period for the BLA and EUA is requested. The first EUA quarterly report was provided to the Agency in July 2021 as per the initial authorization. As indicated above, the next report is scheduled for October 2021. If a waiver is granted, the first BLA LDR would coincide with the January 2022 EUA report.