

1.11.1 Quality Information Amendment

Information concerning mRNA-1273 Drug Product Lot 6008620003 (Catalent Lot 027L20), DOM 01-DEC-2020, is being provided. This lot is subject of a deviation as the result of a leak from the (b) (4) As the leak was (b) (4), the sterile boundary had been breached. No product had been filled at the time of the detection of the leak.

Per a teleconference on December 16, 2020 with FDA (b) (6) (b) (6), the CofA for Lot 6008620003 (Catalent Lot 027L20), the deviation investigation from Catalent (REC 284379), and the technical summary are being provided. The CofA will also be submitted in Section 3.2.P.5.4 as an attachment to that section.

At the request of FDA, this Quality Information Amendment is being simultaneously submitted to IND 19745 and EUA 27073.