

1.11.1 Quality Information Amendment

Information concerning mRNA-1273 Drug Product Lot 7006520014 (Catalent Lot 038K20A), DOM 25-NOV-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 7006520014, the deviation investigation from Catalent (REC 283121), 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.