

**RESPONSE TO CBER COMMUNICATION REGARDING CMC QUESTIONS
RECEIVED ON DECEMBER 08, 2020 FOR EUA 27073**

The Sponsor acknowledges CBER's communication regarding CMC questions which were sent by FDA via email to Carla Vinals on December 08, 2020 for EUA 27073 (Information Request #12).

This document provides the Sponsor's responses to CBER's requests (in **Bold**).

Request for Information for EUA 27073 Dated December 08, 2020

Item 1 from December 08, 2020:

In section 3.2.P.3.5, *Process Validation and/or Evaluation*, of IND 19745, amendment 70, you provided the (b) (4) information for the (b) (4). Please submit the description of cleaning conducted on the (b) (4), prior to (b) (4), to include but not limited to type of cleaning, list of cleaning agents and cleaning agent contact time.

Sponsor Response:

Catalent Indiana, LLC uses several different mechanisms to remove residue as part of the cleaning systems. (b) (4)

(b) (4)

If necessary, (b) (4)

(b) (4)

Item 2 from December 08, 2020:

You stated in your submission that all the product-contact equipment is supplied pre-sterilized, single-use and disposable including the (b) (4). However, in document 3.2.P.3.5, *Process Validation and/or Evaluation*, of IND 19745, amendment 70 (page 17 of 30), you provided the (b) (4) information for the (b) (4). Also, on page 11 of 30 of the same document, you stated, (b) (4)

- a) **Please confirm that the product contact equipment is pre-sterilized, single- use and disposable, and explain why a (b) (4) product pathway. Also, please describe and provide the rationale/purpose for each of the (b) (4)**

Sponsor Response:

Catalent confirms the product contact equipment is pre-sterilized, single-use and disposable. The reference to a (b) (4) was provided in error. The mRNA-1273 process does not utilize a (b) (4).

Prior to filling operations, the following setup and decontamination activities are performed within the (b) (4):

(b) (4)

- b) **If product pathway (b) (4) is to be conducted during the manufacture of mRNA-1273, please provide the (b) (4) Performance Qualification of the product pathway.**

Sponsor Response:

Reference to the (b) (4) was provided in error; therefore, the (b) (4) performance qualification has not been provided.