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## RESPONSE TO FDA REQUEST FOR INFORMATION

### Introduction

An information request was sent by FDA via email to Carla Vinals on November 28, 2020 (concerning comments for IND 19745 SN0070).

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

### **Request for Information for IND 19745 SN0070 Dated November 28, 2020**

**In section 3.2.P.3.5, Process Validation and/or Evaluation, of IND 19745, amendment 70, you provided a high level description of the sterile filtration performed during the drug product manufacture of mRNA-1273 at the Catalent facility in Bloomington, IN. In addition, you reported that sterile filtration validation (bacterial challenge) was performed and documented in EXT-0820, mRNA-1273 Bacterial Challenge Filter Validation Report. Please submit this report or a more detailed description of this validation study.**

### **Sponsor's Response:**

The mRNA-1273 Bacterial Challenge Filter Validation Report ([EXT-0820](#)) is provided as an attachment to this submission.