GERRESHEIMER

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G112
Silver Spring, MD 20993-0002

Primary Packaging Glass

Gerresheimer Glass Inc.
Morganton Plant
114 Wamsutta Mill Road
Morganton, NC 28655
USA

Senior Regulatory Manager
James McFarland

Telephone 1.828.604.1429
E-Mail james.mcfarland @gerresheimer.com
Internet www.gerresheimer.com

Re: Letter of Authorization to reference **Type III DMF #9543**

September 2, 2020

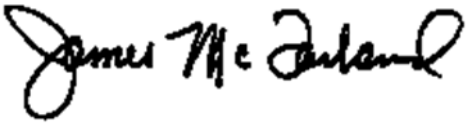
Type I Tubular Containers

Gerresheimer Glass Inc. hereby authorizes Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH, 500 Arcola Road, Collegeville, PA 19436 to incorporate by reference DMF 9543 into any IND, NDA, ANDA, IDE, PMA, ANADA, BLA or DMF filed by Pfizer, Inc..
DMF 9543 was filed by Gerresheimer Glass Inc. on February 7, 1992.

We hereby authorize your office to review the aforementioned specific information in DMF 9543 when considering any IND, NDA, ANDA, BLA, IDE, PMA, ANADA, amendment, or supplement filed by Pfizer, Inc. We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any unauthorized persons without our written consent. This authority is granted for as long as this DMF is active, or until the FDA is notified to rescind the authority.

The materials furnished will be manufactured in accordance with DMF 9543 and in compliance with good manufacturing practices. The DMF holder states that DMF 9543 is current and the holder will comply with the statements made within it. Notification to Pfizer, Inc. and an appropriate notification to FDA and this file will be made for changes that impact the subject materials of this letter.

Yours sincerely,



James McFarland

Senior Regulatory Manager
Gerresheimer Glass Inc.

Adrienne Stafford
Director, Global CMC, Pfizer
4300 Oak Park Road
Sanford, NC 27330
919-566-4701

090177e196a0ecdf\Approved\Approved On: 26-Mar-2021 06:11 (GMT)