Pfizer, Inc.
Attention: Gosia Mineo, M.S.
1 Pfizer Way 190/004/4405
Pearl River, NY 10965

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine,
Reissued on March 29, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic
Act (FDCA) (21 U.S.C. 360bbb-3);
Requests in Amendments submitted and received on March 14, 2022 and April 6, 2022 to
Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine
(Vaccination Providers) - (including Full EUA Prescribing Information)

Dear Ms. Mineo:

This letter is to notify you that we have reviewed the requested changes and data to support the
revisions to your Authorized Fact Sheets and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine
(Vaccination Providers) (Short version) for the two presentations of the Tris/Sucrose formulation
(supplied in multiple dose vials with orange caps and labels with an orange border and in multiple
dose vials with gray caps and labels with a gray border) to include the following new information.

**Vial Storage Prior to Use**
Additional text “for up to 12 months from the date of manufacture” was added to indicate that the
frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F)
for up to 12 months from the date of manufacture.

This Section was also revised to include the updated expiry dates shown below:

<table>
<thead>
<tr>
<th>Printed Manufacturing Date</th>
<th>12-Month Expiry Date</th>
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<tr>
<td>06/2021</td>
<td>31-May-2022</td>
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<td>02/2022</td>
<td>31-Jan-2023</td>
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</tbody>
</table>

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering
Vaccine (Vaccination Providers) (Full EUA Prescribing Information) for consistency.
By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the March 29, 2022 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

--/S/--

Peter W. Marks, M.D., Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research