U.S. FOOD & DRUG ADMINISTRATION

August 12, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and secu United States citizens living abroad, and that involves the virus that causes Coronavirus D 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 2020, declared that circumstances exist justifying the authorization of emergency use of d and biological products during the COVID-19 pandemic, pursuant to Section 564 of the F Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3), subject t terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency U Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,

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[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declar that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, a Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authoriz Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 182 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution f letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made otl technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccinati Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information c monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic s reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact S Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to t storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include

from a developmental toxicity study, and add adverse reactions that have been identified during post authori use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been ident during post authorization use.

10, 2021,[5] and June 25, 2021[6].

On August 12, 2021, having concluded that revising this EUA is appropriate to protect the health or safety under section 564(g)(2) of the Act, FDA again is reissuing the letter in its entirety with revisions incorporated to authorize for emergency use a third dose of the Pfiz BioNTech COVID-19 vaccine administered at least 28 days following the two dose regim this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions are considered to have an equivalent level of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine is for use for active immunization to prevent COVI caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals years of age and older. The vaccine contains a nucleoside-modified messenger RNA (mod encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It investigational vaccine not licensed for any indication.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,0 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline con The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safe from 37,586 of the participants 16 years of age and older, who were followed for a mediar two months after receiving the second dose, did not identify specific safety concerns that preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 c the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on thes and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may b effective. Additionally, FDA determined it is reasonable to conclude, based on the totality scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the preven

[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech vaccine for the prevention of COVID-19 individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, the revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include th following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccina provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administer Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis follow

administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers v
updated to include information about myocarditis and pericarditis following administration of the Pfizer-Bic
COVID-19 Vaccine.

COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with t conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA revie safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 ye age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vacci saline control. FDA's review of the available safety data from 2,260 participants 12 throug years of age, who were followed for a median of 2 months after receiving the second dose not identify specific safety concerns that would preclude issuance of an EUA. FDA's anal SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virolc evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody t participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy d from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infe prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dc (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the pl group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-Bic COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additiona FDA determined it is reasonable to conclude, based on the totality of the scientific evidenc available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 vaccine in individuals 12 years of age or older who have undergone solid organ transplant or individuals 12 years of age or older who are diagnosed with conditions that are conside have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness c reported in two manuscripts on solid organ transplant recipients. The first study was a sing study conducted in 101 individuals who had undergone various solid organ transplant proc (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the BioNTech COVID-19 was administered to 99 of these individuals approximately 2 month they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meetin pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) those who were initially considered to be seronegative and received a third dose of the Pfi BioNTech COVID-19 vaccine; 67/99 (68%) of the entire group receiving a third vaccinati were subsequently considered to have levels of antibodies indicative of a significant respo those who received a third vaccine dose, the adverse event profile was similar to that after second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who l undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver

pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals

approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 mo saline placebo was given to 60 individuals or comparison. The primary outcome was anti- antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challe studies as well as a large clinical cohort study to indicate this antibody titer was protectiv Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binc antibodies indicative of a significant response occurred four weeks after the third dose in 3 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event pro was similar to that after the second dose and no grade 3 or grade 4 adverse events were rep Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive p by Hall et al. demonstrated efficacy of the product in the elderly and persons with co- morbidities) supports the conclusion that a third dose of the Pfizer-Moderna COVID-19 va may be effective in this population, and that the known and potential benefits of a third do Pfizer-BioNTech COVID-19 vaccine outweigh the known and potential risks of the vacci immunocompromised individuals at least 12 years of age who have received two doses of Pfizer-BioNTech COVID-19 vaccine and who have undergone solid organ transplantation who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Having concluded that the criteria for issuance of this authorization under Section 564(c) Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (S II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, beca

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, includ severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to b that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVI and that, when used under the conditions described in this authorization, the kno potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative to the emergency use o Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[7]

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authoriza limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directl through authorized distributor(s)[8], to emergency response stakeholders[9] as directed by the U.S. government, including the Centers for Disease Contro Prevention (CDC) and/or other designee, for use consistent with the terms conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization w administered by vaccination providers[10] and used only to prevent COVID- individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccinati provider without an individual prescription for each vaccine recipient.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple d vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, U prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not conta preservative.

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[8] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[9] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its deleg have legal responsibility and authority for responding to an incident, based on political or geographical boun lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public he range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), th might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in official capacity under the authority of the state health department to administer COVID-19 vaccines). In su it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccina providers will all be met.

[10] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provide licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CD COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" provider that is authorized to administer this vaccine in accordance with the laws of the country in which it i administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeas against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS A

State-authorized pharmacy interns acting under the supervision of a qualified pharmacist)." Dec. Sig. HHS. *Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 202

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucle
modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-
Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingred
lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.0
2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glyc
phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic
potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydr
and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additiona
mg sodium chloride per dose.

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be
administered at least 28 days following the second dose of the two dose regimen of this va
to individuals 12 years of age or older who have undergone solid organ transplantation, or
individuals 12 years of age or older who are diagnosed with conditions that are considered
have an equivalent level of immunocompromise.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to thos
facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked
"Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized
distributed, stored, further redistributed, and administered by emergency response stakeho
when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite
fact that the vial and carton labels may not contain information that otherwise would be re
under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following
product-specific information required to be made available to vaccination providers and
recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Provider
Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to
Coronavirus Disease 2019 (COVID-19)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of
Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COV
in Individuals 12 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe tha
the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prev
COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh
known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19

Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNT COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criter forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consiste with, and may not exceed, the terms of the Authorization, including the Scope of Authorizatior (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Sec 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in indivic 12 years of age and older as described in the Scope of Authorization (Section II) under this EU despite the fact that it does not meet certain requirements otherwise required by applicable fede law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authoriza

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. governmer including CDC and/or other designee, and the authorized labeling (i.e., Fact She will be made available to vaccination providers, recipients, and caregivers consi with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and chain is maintained until delivered to emergency response stakeholders' receipt

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all releva stakeholders (e.g., emergency response stakeholders, authorized distributors, an vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakehol copy of this letter of authorization and communicate any subsequent amendmen might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's r and concurrence, when necessary to meet public health needs during an emerge

and concurrence, when necessary to meet public health needs during an emerge
Any instructional and educational materials that are inconsistent with the author
labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Sheets for the Pfizer COVID-19 Vaccine. Any request for changes to this EUA be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[11]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported t Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no late 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic sa report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, s populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether not associated with an adverse event, that were identified since the last repor interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for exam changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturin process, facilities, or equipment without notification to and concurrence by the Agency.

I. All manufacturing facilities will comply with Current Good Manufacturing Prac requirements.

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[11] The following types of revisions may be authorized without reissuing this letter: (1) changes to the author labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, includi fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authoriza require data collection or study. For changes to the authorization, including the authorized labeling, of the t listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team

(PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threat
(OCET)/Office of the Chief Scientist (OCS).

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each d product lot at least 48 hours prior to vaccine distribution. The CoA will include established specifications and specific results for each quality control test perfor on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot numb manufacturing site, date of manufacture, and lot disposition, including those lots were quarantined for investigation or those lots that were rejected. Information reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon reques records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified l adverse events of special interest, along with deaths and hospitalizations, and se COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations w specific comorbidities. The studies should be conducted in large scale databases an active comparator. Pfizer Inc. will provide protocols and status update report the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive autho Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administra consistent with the terms of this letter and CDC's COVID-19 Vaccination Progr

P. Emergency response stakeholders will ensure that vaccination providers within jurisdictions are aware of this letter of authorization, and the terms herein and ar subsequent amendments that might be made to the letter of authorization, instru them about the means through which they are to obtain and administer the vacci under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Heal Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVI Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training requir CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers each individual receiving vaccination and provide the necessary information for receiving their second dose.

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine mus report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in children and adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include t words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description secti the report. More information is available at vaers.hhs.gov or by calling 1-8(7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1 by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-833

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse eve the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergenc response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirement concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA maintained until notified by FDA. Such records will be made available to C and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to t use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronav Disease 2019 (COVID-19) for use in individuals 12 years of age and olde
- The emergency use of this product is only authorized for the duration of th declaration that circumstances exist justifying the authorization of emerge use of the medical product under Section 564(b)(1) of the FD&C Act unle declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the product is exported from the United States, conditions C, D, and O throug do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended u the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (Fact Sheets) be made available to vaccination providers, recipients, and caregive condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under S 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist

Chief Scientist
Food and Drug Administration

Enclosures