



Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Division of Epidemiology (DE)

PHARMACOVIGILANCE EUA MEMORANDUM

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Through: Manette Niu, MD
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Subject: Review of Pharmacovigilance Plan

Sponsor: Pfizer

Product: Pfizer-BioNTech COVID-19 Vaccine*

Application Type/Number: EUA 27034.132

Proposed Indication: Active immunization to prevent COVID-19 in
individuals 12 years of age or older

Submission Date: April 9, 2021

Action Due Date: May 7, 2021

*The product was also referred to as BNT162b2 in the clinical development

1 OBJECTIVE

The purpose of this review is to assess the adequacy of the plan for active surveillance and pharmacovigilance activities for the expanded indications of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 - 15 years of age.

2 PRODUCT INFORMATION

2.1 Product Description

The Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose. The product is a frozen suspension for intramuscular injection.

The product is administered as a series of two doses (0.3 mL) each 21 days apart by intramuscular injection.

2.2 Authorized indication

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2.3 Proposed indication

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

3 PERTINENT REGULATORY HISTORY

The Sponsor submitted a rolling Marketing Authorization Application on October 5, 2020 to the European Medicines Agency. Feedback on pharmacovigilance methods and active surveillance plans was provided in IND19736.84, IND19736.91, IND19736.113, IND19736.121, and IND19736.125.

On December 2, 2020, the product was authorized in the United Kingdom. On December 9, 2020, in response to cases of possible anaphylaxis occurring during their mass vaccination efforts, UK regulators issued a guidance stating that the vaccine should not be given to any person with a history of a significant allergic reaction to a vaccine, medicine, or food. In addition, they advised resuscitation facilities should be available at all times for all vaccinations. The product was authorized under an EUA by FDA on December 11, 2020. FDA received several reports of anaphylaxis shortly after

authorization. The Sponsor submitted an updated pharmacovigilance plan (PVP) to EUA27034.57 adding anaphylaxis as an Important Identified Risk per FDA request. The product has received temporary authorization for emergency supply in 30 countries and conditional marketing authorization in 40 countries.

The Sponsor added the terms “pain in extremity (arm)”, “vomiting”, and “diarrhea” to Section 6.2 of the product labeling (EUA27034.105).

4 DESCRIPTION OF PRODUCT SAFETY DATABASE

4.1 Clinical studies

This EUA amendment presents data from the Phase 3 Study C4591001 for adolescents ages 12 - 15 years to a data lock point (DLP) of March 13, 2021. Study C4591001 is an ongoing randomized, placebo-controlled, Phase 1/2/3 study, which is summarized in **Table 1** below. Among participants ages 12 - 15 years of age, 1124 participants received two doses of BNT162b2 and seven received one dose of BNT162b2 (total n = 1131) compared to 1129 who were randomized to placebo. There were 49 participants who originally received placebo, then received Pfizer-BioNTech COVID-19 vaccine in an open-label follow-up period after unblinding.

Table 1. Summary of clinical studies supporting the safety and efficacy of Pfizer-BioNTech COVID-19 vaccine*

Study	Description	N
C4591001	Phase 1/2/3 randomized, observer-blind, placebo control	
	Phase 1: Adults 18 - 55, and 65 - 85 years of age. BNT162b2 was evaluated at three dose levels (10, 20, 30 µg), or placebo	Phase 1: 90 randomized 4:1 within each dose/age group
	Phase 2: Adults 18 - 55, and 56 - 85 years of age. Subjects were given 30 µg BNT162b2 or placebo.	Phase 2: 360 randomized 1:1
	Phase 3: Adolescents and adults 12 - 15, 16 - 55, and > 55 years of age	Phase 3: ~46,000 randomized 1:1 (includes 360 subjects from Phase 2)

*Adapted from Table 1, EUA Request for Pfizer-BioNTech COVID-19 Vaccine Use in Individuals 12 - 15 Years of Age, EUA27034.132, Module 1.19

All participants 12 - 15 years of age and a subset of participants ≥ 16 years of age recorded reactogenicity events that included solicited assessment of injection site reactions such as pain, redness, or swelling, as well as systemic adverse events (AEs) that included fever, fatigue, chills, headache, vomiting, diarrhea, muscle or joint pain, and antipyretic/pain medication use for 7 days using an electronic diary. AEs were

recorded for up to one month following Dose 2 and characterized by frequency, severity, seriousness, and relatedness to study intervention. Serious AEs (SAEs) will be recorded up to 6 months after Dose 2, and deaths will be recorded to the completion of the study.

4.2 Adverse events

Local reactions were more common in vaccinated compared to placebo participants, and occurred at similar frequencies in adolescents (ages 12 - 15 years) and young adults (ages 16 - 25 years). The most common local reaction was pain at the injection site, followed by swelling and redness.

Systemic AEs occurred at similar frequencies in adolescent participants compared to young adult participants, were more common in vaccinated subjects, and were generally higher after the second dose. Common systemic AEs included fatigue, headache, chills, muscle and joint pain, and fever. Vomiting and diarrhea were reported at similar frequencies in vaccinated and placebo recipients. Lymphadenopathy was more common in the vaccine group (n = 7) compared to the placebo group (n = 1).

Severe AEs in adolescents occurred at a frequency of 0.6% in the BNT162b2 and 0.2% in the placebo group from Dose 1 to one month after Dose 2. Two adolescent participants had Grade 4 AEs, which were:

- Focal peritonitis and appendicitis in a placebo group participant that occurred 19 days after Dose 2.
- Grade 4 pyrexia (40.4 °C) in an adolescent participant in the BNT162b2 group that occurred two days after Dose 1 with a duration of three days. This participant withdrew from the study.

There were also two adolescent participants with Grade 4 AEs that occurred after they turned 16 years of age and were unblinded to receive BNT162b2, which were:

- Anaphylactoid reaction in a participant who was initially randomized to placebo, which occurred three days after the first dose of BNT162b2.
- Depression in a participant who was initially randomized to placebo, which occurred seven days after the first dose of BNT162b2. This was considered a SAE due to hospitalization.

SAEs in adolescents from Dose 1 to the DLP were reported in the BNT162b2 group consisting of two participants with depression, one participant with concurrent events of anxiety and depression, one participant with suicidal ideation, and one participant with neuralgia, abdominal pain, and constipation. There were two non-serious AEs of depression in the placebo group. One participant in the placebo group had a SAE of focal peritonitis and appendicitis, and another participant in the placebo group also had appendicitis.

There were no deaths in adolescents (ages 12 - 15 years) or in young adults (16 - 25 years of age) as of March 13, 2021. One participant in the BNT162b2 group withdrew from the study due to an AE of pyrexia.

The following adverse events of clinical interest were reported:

- There were no cases of anaphylaxis or anaphylactoid reactions during blinded follow-up as of the DLP in adolescents. One participant who was initially randomized to placebo experienced an anaphylactoid reaction three days after receiving BNT162b2.
- Seven adolescent participants (0.6%) in the BNT162b2 group and one participant (0.1%) in the placebo group had lymphadenopathy. Most of these occurred in the arm and neck and were reported within 2 - 10 days after vaccination.
- Two participants in the placebo group had events of appendicitis.
- There were no cases of facial paralysis in adolescents.

In addition, there were no severe COVID-19 cases reported in adolescents 12 - 15 years of age. There were also no reports of pregnancy in participants ages 12 - 15 years.

5 FDA ANALYSIS OF POST-AUTHORIZATION EXPERIENCE

As of April 20, 2021, 8,472 Pfizer-BioNTech COVID-19 adverse event reports categorized as serious have been received and processed (coded, redacted, and quality assurance performed) by the Vaccine Adverse Event Reporting System (VAERS). The most common preferred terms (PTs) among all VAERS reports are headache (n = 9,126, 8.9%), chills (n = 6,723, 6.6%), fatigue (n = 6,720, 6.6%), pyrexia (6,565, 6.5%), pain (n = 6,236, 6.1%), nausea (n = 5,107, 5.0%), dizziness (n = 4,671, 4.6%), pain in extremity (n = 3,410, 3.3%), myalgia (n = 3,225, 3.2%), and dyspnoea (n = 2,624, 2.6%). Other than anaphylaxis (discussed below), FDA review of VAERS reports, including serious and death reports, has not identified new safety concerns.

A search of VAERS was performed on April 20, 2021 for reports after Pfizer-BioNTech COVID-19 Vaccine in individuals ages 12 - 15 years, which returned 24 reports. All reports were non-serious and reported from the U.S. Twenty-one (87.5%) reports describe patients who were given the vaccine below the authorized age of 16 years in the absence of an AE. The remaining three VAERS reports in individuals ages 12 -15 years were:

- Thirteen year old female who developed chills, generalized muscle pain, sore throat, nausea, fatigue, and fever the same day of vaccination.
- Fifteen year old female given incorrect dose of vaccine. No AE was reported.
- Fifteen year old female given second dose too early. No AE was reported.

Data mining query with the Empirica Signals Management run was performed on April 21, 2021 for each of the four Main Views (All Signals from Age Groups, All Signals from Gender, All Signals from Serious/Fatal, and All Signals from US/All VAERS). The data lock point was April 16, 2021. The alert score for disproportional reporting uses the lower bound of 95% confidence interval of Empirical Bayesian geometric mean, EB05 > 2.0. An EB05 of 2.064 was found for the PT 'Body Temperature' in adults ages 45 - 64.9 years of age. There were no other PTs with an EB05 > 2.0.

Reviewer comment: Analysis of VAERS data did not identify any new safety concerns.

6 SPONSOR'S PHARMACOVIGILANCE PLAN (PVP)

A summary of the Sponsor's pharmacovigilance plan (PVP) is provided in **Table 2** below which describes the important identified and potential risks, and missing information for Pfizer-BioNTech COVID-19 Vaccine. The Sponsor will conduct both passive and active surveillance activities for the safety concerns listed below.

Table 2 Sponsor's Pharmacovigilance Plan

Type of Concern	Safety Concern	Proposed Action
Identified	Anaphylaxis	<ul style="list-style-type: none">▪ Pharmacovigilance▪ Labeling▪ Data capture aid▪ Completion of the Phase 1/2/3 randomized, placebo-controlled study evaluating safety and efficacy (Study C4591001)▪ Study C4591009: A non-interventional post-approval safety study in the U.S.▪ Study C4591011: Active safety surveillance in the U.S. Department of Defense▪ Study C4591012: Active safety surveillance in the Veteran's Affairs Health System
Potential	Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)	<ul style="list-style-type: none">▪ Pharmacovigilance▪ Mandatory reporting of cases of COVID-19 that result in hospitalization or death▪ Data capture aid▪ Completion of the Phase 1/2/3 randomized, placebo-controlled study evaluating safety and efficacy (Study 4591001)▪ Three post-authorization safety studies to perform long-term active surveillance for safety events of interest among subjects administered Pfizer-BioNTech COVID-19 vaccine (Studies C4591008, C4591011, C4591012)

		<ul style="list-style-type: none"> ▪ Study 4591009: A non-interventional post-approval safety study in the U.S.
Missing	Use in pregnancy and lactation	<ul style="list-style-type: none"> ▪ Pharmacovigilance ▪ Study C4591015: Phase 2/3 placebo-controlled, randomized trial in pregnant women ≥ 18 years ▪ Active surveillance studies to monitor vaccine-exposed pregnancies under EUA within the U.S.
Missing	Vaccine effectiveness	<ul style="list-style-type: none"> ▪ Pharmacovigilance ▪ Mandatory reporting of cases of COVID-19 that result in hospitalization or death ▪ Data capture aid ▪ Study C4591014: Non-interventional study to evaluate effectiveness against COVID-19 among individuals >16 years of age in a real-world setting (Kaiser Permanente Southern California health system) ▪ WI235284: Low-interventional test-negative design study to evaluate effectiveness in individuals ≥ 18 years of age in a real-world setting (Atlanta, GA) ▪ WI255886: Low-interventional test-negative design study to evaluate effectiveness among individuals >18 years of age in a real-world setting (Bristol, UK) ▪ BTN162-01 cohort 13: Immunogenicity study in immunocompromised subjects
Missing	Use in pediatric individuals < 12 years of age	<ul style="list-style-type: none"> ▪ Pharmacovigilance ▪ Continuation of Study C4591001 in ≥ 12 to ≤ 15 years: Phase 1/2/3 randomized, placebo-controlled study

		<ul style="list-style-type: none"> ▪ Study C4591007: Phase 1 open label dose finding study and phase 2/3 placebo-controlled study in healthy children < 12 years of age ▪ Study 4591009: A non-interventional post-approval safety study in the U.S.
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*Adapted from Tables 36 - 41, Pharmacovigilance Plan for Emergency Use Authorization 27034, EUA27034.132, Module 1.16.1

6.1 Post-authorization active surveillance studies

Three active safety surveillance studies were proposed in the original EUA submission. These studies were an evaluation of the rates of adverse events of interest by surveying healthcare workers (Study C4591008), from electronic health records (EHRs) and medical service claims within the Department of Defense (DoD) Health System Databases (Study C4591011), and EHR and claims data from the Veteran's Affairs Health System (Study C4591012). Please refer to the Pharmacovigilance EUA Review Memorandum (EUA27034.0) for an initial review of these studies. The final protocols for these three active surveillance studies were submitted to EUA27034.68. The Sponsor also submitted three post-authorization Vaccine Effectiveness studies (C4591014, WI235284, WI255886) to IND19736.268, which are being reviewed by the CBER Biologics Effectiveness and Safety (BEST) team. According to a response to an Information Request submitted to IND19736.305, the Sponsor plans to amend the Study Protocol C4591014 on vaccine effectiveness to include adolescents ages 12 - 15 years.

The Sponsor proposes Study C4591009, which is a post-approval observation study using real-world data to assess the association between the Pfizer-BioNTech COVID-19 Vaccine and safety events of interest among persons administered the vaccine in the U.S. population and in populations of interest such as pregnant women, immunocompromised persons, and in persons with a prior history of COVID-19 infection. The study population will include subjects ages <12 and 12 - 15 years of age. This study will use electronic health records and claims data from data partners participating in the Sentinel System. The proposed milestones for this study are:

- Protocol submission: August 31, 2021
- Monitoring report submission: October 31, 2022
- Interim analysis submission: October 31, 2023
- Final study report submission: October 31, 2025

7 ANALYSIS OF SPONSOR'S PHARMACOVIGILANCE PLAN

A complete review of the PVP and plans for active surveillance may be found in the OBE/DE EUA Pharmacovigilance Memorandum for EUA27034/0. This review will focus on changes made to the PVP since EUA authorization. These changes include addition

of anaphylaxis as an important identified risk and modification of missing information in pediatric subjects.

7.1 Important Identified Risks

7.1.1 Anaphylaxis

On December 9, 2020, FDA was notified of two cases of possible anaphylactic reactions that occurred in the U.K. during mass vaccination. A brief summary of these two cases is as follows:

- 49 year-old female who developed throat closing and tongue swelling within minutes after vaccination. The patient received intramuscular (IM) epinephrine and chlorphenamine, and two doses of nebulized epinephrine. The patient was observed in the emergency department overnight. The patient has a history of egg allergy.
- 40 year-old female who developed wheezing and tachycardia. She was administered three doses of IM epinephrine. The patient has a prior history of unspecified reactions to drugs.

A third individual with no prior history of allergies had what was described as mild allergic reaction and was treated with an antihistamine. It was estimated that 15,000 individuals received the vaccine in the UK at the time of these adverse events.

In response to cases of possible anaphylaxis occurring during their mass vaccination efforts, UK regulators issued a guidance on December 9, 2020 stating that the vaccine should not be given to any person with a history of a significant allergic reaction to a vaccine, medicine, or food. In addition, they advised resuscitation facilities should be available at all times for all vaccinations.

Shortly after the issuance of the EUA, FDA received several reports of anaphylaxis following administration of the Pfizer-BioNTech COVID-19 Vaccine. Anaphylaxis was not included in the Sponsor's PVP in the original EUA submission. Given that anaphylaxis rarely occurs after vaccination, with an expected incidence of approximately one per million doses (1) and thus may be occurring more frequently than expected after administration of the Pfizer-BioNTech COVID-19 Vaccine, the Sponsor was requested by FDA to add anaphylaxis to the PVP. The Sponsor submitted an updated PVP (EUA27034.57) that adds anaphylaxis as an Important Identified Risk. The Sponsor developed a data capture aid to facilitate capture of clinical details regarding potential anaphylaxis cases. This data capture aid includes fields for clinical symptoms, time to onset relative to vaccination, hospitalization and level of care, laboratory tests, prior history of allergic reactions, and treatment received. The EUA label communicates the risk of anaphylaxis and links healthcare providers to management guidelines by CDC. The post-authorization active surveillance studies also collect information on anaphylaxis.

Cases of anaphylaxis in the post-authorization experience are monitored by the Centers for Disease Control and Prevention (CDC) and FDA. Incoming VAERS reports are screened by CDC for potential cases of anaphylaxis. Additional clinical details are

obtained by CDC staff by contacting the VAERS reporter and through review of medical records. Cases are classified as anaphylaxis using Brighton criteria (2). A case that meets the definition of Brighton levels 1 - 3 is considered a case of anaphylaxis. Given the complexity of the Brighton criteria that require detailed clinical information, cases of anaphylaxis identified and classified by CDC are used. As of April 26, 2021, there have been 56 confirmed cases of anaphylaxis following the Pfizer-BioNTech COVID-19 Vaccine. Of the 56 cases, 51 (91.1%) are female and five (8.9%) are male. The median age is 39 years (range 27 - 67 years, unreported in one case). The time to onset from vaccination to the onset of symptoms of anaphylaxis ranged from immediately to 19 hours (unreported in three cases). Twenty-three (41.1%) cases met the criteria for Brighton Level 1, 30 (53.6%) were Brighton Level 2, and three (5.4%) were Brighton Level 3. As of April 26, 2021, a total of 120,774,248 doses of Pfizer-BioNTech COVID-19 Vaccine have been administered for an anaphylaxis reporting rate of 0.46 per million doses.

Reviewer comment: The Sponsor's addition of anaphylaxis to the important identified risks is acceptable. At this time, there is no evidence to suggest individuals 12 - 15 years of age will have an increased risk of anaphylaxis following the Pfizer-BioNTech vaccine than other age groups.

7.2 Important Missing Information

7.2.1 Use in Pediatric Individuals <12 years of Age

The PVP in the first EUA authorization included "Use in Pediatric Individuals <16 Years of Age", which has been updated to "Use in Pediatric Individuals <12 Years of Age". Pediatric subjects younger than 12 years of age were excluded from the pivotal clinical studies. The Sponsor plans additional clinical studies of safety, efficacy, and immunogenicity in subjects under the age of 12. The Sponsor also plans to note that limited data are available from pediatric subjects in the product labeling.

Reviewer comment: The Sponsor's plan to perform additional studies in pediatric subjects and note the limited data in the product labeling is acceptable.

8 DE ASSESSMENT

The Sponsor's safety specifications adequately address the safety concerns identified from the clinical studies and post-authorization experience. The *Fact Sheet for Vaccination Providers* instructs healthcare providers of the mandatory reporting to VAERS of cases of COVID-19 resulting in death or hospitalization, MIS, SAEs, and medication errors. The Sponsor will conduct active surveillance studies to characterize adverse events after vaccination as well as studies of vaccine effectiveness. The Sponsor's plan for active surveillance and pharmacovigilance activities under EUA is acceptable.

9 DE RECOMMENDATIONS

1. Mandatory reporting by the Sponsor of the following events to Vaccine Adverse Event Reporting System (VAERS) within 15 days:
 - Serious adverse events (irrespective of attribution to vaccination)

- Cases of Multisystem Inflammatory Syndrome in children
 - Cases of COVID-19 that result in hospitalization or death
2. The Sponsor will conduct periodic aggregate review of safety data and submit periodic safety reports at monthly intervals. Each periodic safety 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, special populations (e.g., pregnant women), and adverse events of special interest
 - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval
 - Newly identified safety concerns in the interval
 - Actions taken since the last report because of adverse experiences (for example, changes made to Vaccination Provider fact sheets, changes made to studies or studies initiated)
3. The Sponsor will conduct one or more post-authorization observational study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA amendment to include individuals 12 – 15 years of age in the general U.S. population, populations of interest such as pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. The Sponsor will provide protocols and status update reports with agreed-upon study designs and milestone dates. The Sponsor has proposed the following planned active surveillance study that will include adolescents ages 12 - 15 years:
- Study Protocol Number C4591009. This is a post-approval observation study using real-world data to assess the association between the Pfizer-BioNTech COVID-19 vaccine and safety events of interest among persons administered the vaccine in the U.S. population and in populations of interest such as pregnant women, immunocompromised persons, and in persons with a prior history of COVID-19 infection. The study population will include subjects ages <12 and 12 - 15 years of age. This study will use electronic health records and claims data from data partners participating in the Sentinel System (anticipated protocol submission August 31, 2021).
- Of note, the Sponsor submitted a clinical study protocol to assess safety and immunogenicity in pregnant women and has proposed active surveillance studies designed to monitor vaccination during pregnancy within populations expected to receive the vaccine under EUA.

4. The Sponsor submitted a protocol for a vaccine effectiveness study:
 - Study Protocol Number C4591014. This study estimates vaccine effectiveness of two doses of the Pfizer-BioNTech COVID-19 vaccine against hospitalization due to SARS-CoV-2 infection in individuals ≥ 16 years of age. Other objectives include evaluation of vaccine effectiveness after one dose, Emergency Department admission, specific variants, and other populations of interest. This study will utilize the Kaiser Permanente Southern California database. According to a response to an Information Request (IND19736.305), the Sponsor plans to amend this protocol to include patients ages 12 - 15 years.
5. Active surveillance of vaccine recipients via the v-safe program. V-safe is a new smartphone-based opt-in program that uses text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow-up to anyone who reports medically significant (important) adverse events. The system is currently designed for use by adults. Responses indicating missed work, inability to do normal daily activities, or that the recipient received care from a doctor or other healthcare professional will trigger the VAERS Call Center to reach out to the participant and collect information for a VAERS report, if appropriate. V-safe may be modified to allow adolescents to self-register and report to v-safe, and a pathway created for a parent/guardian to report on behalf of younger children.

REFERENCES

1. McNeil MM, Weintraub ES, Duffy J, Sukumaran L, Jacobsen SJ, Klein NP, et al. Risk of anaphylaxis after vaccination in children and adults. *J Allergy Clin Immunol*. 2016;137(3):868-78.
2. Rugeberg JU, Gold MS, Bayas JM, Blum MD, Bonhoeffer J, Friedlander S, et al. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine*. 2007;25(31):5675-84.

APPENDIX
Materials Reviewed

Table A1: Materials reviewed in support of this assessment

Date	Source	Document Type	Document(s) Reviewed
April 9, 2021	Sponsor	EUA27034.132	Module 1.16.1, Pharmacovigilance Plan
April 9, 2021	Sponsor	EUA27034	Module 1.19, EUA
April 9, 2021	Sponsor	EUA27034	Module 1.14.1.3, Fact sheet for Health Care Providers