

From: Naik, Ramachandra
Sent: Monday, May 10, 2021 8:57 AM
To: 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Subject: RE: EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments on Fact Sheet for Vaccination Providers-Full EUA Prescribing Information (EUA 27034.160 submission)

Good morning Elisa!

Your proposal regarding the complementary revision to the Fact Sheet for Recipients and Caregivers, as described below, is acceptable to CBER. Please submit the revised Fact Sheets and Full EUA PI as soon as possible.

Please confirm receipt of this email and let us know if you have any questions or need additional information.

Regards,
Ram

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Friday, May 07, 2021 7:37 PM
To: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Subject: [EXTERNAL] RE: EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments on Fact Sheet for Vaccination Providers-Full EUA Prescribing Information (EUA 27034.160 submission)
Importance: High

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Good Evening Ram,

We accept CBER's revisions for the HCP Fact Sheet/EUA PI. We are proposing a complementary revision to the Recipient and Caregiver Fact Sheet. I am sending these back to you via email for expedience. The language for the HCP Fact Sheet/EUA PI below is CBER's language. I just reincluded it here for ease of review of the Recipient and Caregiver Fact Sheet proposal. We will submit the updated labels formally on Monday. We would appreciate it if CBER would let us know if there are any issues with the changes proposed for the Recipient and Caregiver Fact Sheet though so we can address these before the formal submission. I suggest a time frame of CBER alerting us to any changes to the Recipient and Caregiver Fact Sheet language as soon as possible, but by no later than 10 am Monday so that we could still submit "final" labels formally by Monday afternoon. If "no objection" from CBER were to come over the weekend we can submit formally on Monday morning. If you have any questions or concerns please let me know.

Combined EUA Fact Sheet for HCP and EUA Prescribing Information:

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Fact Sheet for Recipients and Caregivers:

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- **have ever fainted in association with an injection**

Best regards,
Elisa

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>

Sent: Friday, May 7, 2021 12:57 PM

To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>

Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>

Subject: [EXTERNAL] RE: EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments on Fact Sheet for Vaccination Providers-Full EUA Prescribing Information (EUA 27034.160 submission)

Dear Elisa,

Please see below for CBER's suggested revised comment regarding syncope.

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Please confirm receipt of this message and let me know if you have any questions or need additional information.

Regards,
Ram

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Thursday, May 06, 2021 4:31 PM
To: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Subject: [EXTERNAL] RE: EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments on Fact Sheet for Vaccination Providers-Full EUA Prescribing Information (EUA 27034.160 submission)
Importance: High

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Dear Laura & Ram,

With reference to the label revisions sent below and the teleconference we had to discuss these this afternoon, below is our proposed language. We would appreciate it if you could provide response to our proposal by 10am tomorrow morning.

"In adolescents, syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid failing injury. Vaccinees should be observed for at least 15 minutes after vaccine administration."

Best regards,
Elisa

From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Wednesday, May 5, 2021 3:51 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Subject: [EXTERNAL] EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments on Fact Sheet for Vaccination Providers-Full EUA Prescribing Information (EUA 27034.160 submission)

Dear Ms. Aghajani Memar,

The attached Word document contains CBER edits and comments on your revised *Fact Sheet for Vaccination Providers - Full EUA Prescribing Information* submitted to EUA 27034 in amendment 160 on May 3, 2021. Please submit the revised *Fact Sheet for Vaccination Providers - Full EUA Prescribing Information* in an amendment to your EUA 27034 by COB Thursday, May 6, 2021.

Note: Please include our colleague, CAPT Michael Smith, Ph.D. (copied on the message), in all communications related to IND 19736 and EUA 27034.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Best Regards,
Laura

Laura Gottschalk, PhD

Regulatory Project Manager/Primary Reviewer

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
laura.gottschalk@fda.hhs.gov



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