

Laura B. Gottschalk -S
2021.05.07 13:04:11 -04'00'

From: Naik, Ramachandra
Sent: Friday, May 07, 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: 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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