

**From:** Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>  
**Sent:** Friday, August 20, 2021 1:51 PM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
**Cc:** Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Subject:** STN 125742/0 : 7th set of PI labeling comments and request for table with subjects who reported unsolicited AEs during blinded follow-up in study C4591001 - Please respond by COB Today

Dear Elisa,

Attached is the 7<sup>th</sup> set of comments from the review team on the Package Insert (PI). Additionally, we have the following information request:

Please complete the following table to summarize the numbers and percentages of BNT162b2 and placebo recipients, by age group and study period, who reported the indicated categories of unsolicited adverse events during blinded follow-up in study C4591001. Please use denominators of the corresponding population in each column and please do not report percentages in 100/PY. .

<b>EVENT</b>	<b>BNT162b2 ≥16-55 n/N (%)</b>	<b>BNT162b2 &gt;55 years n/N (%)</b>	<b>Total BNT162b2 ≥16 years n/N (%)</b>	<b>Placebo ≥16-55 n/N (%)</b>	<b>Placebo &gt;55 years n/N (%)</b>	<b>Total Placebo ≥16 years n/N (%)</b>
<b>From Dose 1 through 1 month Dose 2</b>						
Any unsolicited adverse event						
Unsolicited non-serious AEs						
SAEs						
Withdrawal due to unsolicited AEs						
Death						
<b>From Dose 1 to cutoff date or participant unblinding</b>						

<b>(whichever is earlier)</b>					
Any unsolicited adverse event					
Unsolicited non-serious AE					
SAEs					
Withdrawal due to unsolicited AEs					
Deaths					

Please email us the further revised PI (both Word tracked-changes and Word annotated) and completed table by **COB today, August 20, 2021**, and follow up with a submission to the BLA.

Please acknowledge receipt of this communication and let me know if you have any questions.

Best,  
 Laura

**Laura Gottschalk, PhD**

*Regulatory Project Manager/Primary Reviewer*

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