

Laura B. Gottschalk -S  
2021.11.12 16:10:14 -05'00'

**From:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Sent:** Friday, November 12, 2021 1:38 PM  
**To:** Patel, Amit <Amitkumar.Patel@pfizer.com>  
**Cc:** Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>  
**Subject:** RE: Re: COVID BLA 125742 - Question relating to the 508 tables - sBLA 12-15 years

Dear Mr. Patel,

Attached Word document contains shell tables to include the efficacy and other clinical data for sBLA for adolescents ages 12 through 15 years.

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

Regards,  
Ram

**Ramachandra S. Naik, Ph.D.**

*Biologist (Regulatory) / Primary Reviewer*  
Center for Biologics Evaluation and Research  
Office of Vaccines Research and Review  
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[ramachandra.naik@fda.hhs.gov](mailto:ramachandra.naik@fda.hhs.gov)



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**From:** Naik, Ramachandra  
**Sent:** Thursday, November 11, 2021 6:32 PM  
**To:** Patel, Amit <[Amitkumar.Patel@pfizer.com](mailto:Amitkumar.Patel@pfizer.com)>  
**Cc:** Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>; Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>; Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>  
**Subject:** RE: Re: COVID BLA 125742 - Question relating to the 508 tables - sBLA 12-15 years

Dear Amit,

Confirming receipt. We will discuss with the review team regarding your proposal to provide the 508-compliant tables.

As suggested, we will continue to include Elisa and Carmel in any correspondence in your absence.

Regards,  
Ram

**From:** Patel, Amit <[Amitkumar.Patel@pfizer.com](mailto:Amitkumar.Patel@pfizer.com)>  
**Sent:** Thursday, November 11, 2021 4:31 PM  
**To:** Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>  
**Cc:** Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>; Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>; Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>  
**Subject:** [EXTERNAL] RE: Re: COVID BLA 125742 - Question relating to the 508 tables - sBLA 12-15 years

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Hi Ram,

Apologies in my haste to send the email I omitted the relevant clarifying background information. In the attached CBER correspondence *CBER responses to the Request for Comments and Advice regarding the supplemental BLA for adolescents 12 through 15 years of age* dated 24 September 2021 (IND 19736 amendment 434), CBER has made specific reference to also be providing shell tables specific to this sBLA submission for individuals  $\geq 12$  years of age (page 4).

Pfizer/BioNTech is alternatively proposing to deliver the 508 table outputs (covering only 12-15 years subjects) based on the previous submitted 508 shell tables for the upcoming sBLA 12-15 years planned for 17 December 2021.

Please let me know if you have any questions or concerns,

Thanks  
Amit

**From:** Patel, Amit  
**Sent:** Thursday, November 11, 2021 2:59 PM  
**To:** Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>  
**Cc:** Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>; Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>; Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>  
**Subject:** Re: COVID BLA 125742 - Question relating to the 508 tables - sBLA 12-15 years

Hi Ram,

Pfizer/BioNTech proposes to deliver the 508 table outputs (covering only 12-15 years subjects) based on the previous submitted 508 shell tables for the upcoming supplemental BLA 12-15 years submission planned for 17 December 2021.

Please let me know if you have any questions or concerns or would like to discuss further in a call. Also I wanted to take this opportunity to notify you that I (b) (6) inclusive. Please continue to include Elisa and Carmel in any correspondence (b) (6)

Thanks  
Amit

**Amit Patel**  
Director

Global Product Development  
Global Regulatory Affairs - Vaccines  
M: (214) 918 5262

