

From: Gottschalk, Laura
Sent: Saturday, August 21, 2021 11:11 AM
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 - Final Draft Labels: Carton and Containers

Dear Ms. Harkins,

We have reviewed your draft Carton and Container labels submitted in Amendment 63 to your BLA, dated August 19, 2021 (STN 125742/0.63; Seq 0064) and found them to be acceptable. CBER considers the Carton and Container labels included in Amendment 63 as the Final Draft Labels for approval.

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
Tel: 301-796-0798
laura.gottschalk@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.