

**From:** [Resnick, Josephine](#)  
**To:** [Michelle Olsen](#)  
**Cc:** [Kulinski, Joseph](#); [Agnihothram, Sudhakar](#)  
**Subject:** 125752 IR #49 (labeling) - please respond by 1:30 PM today  
**Date:** Friday, January 28, 2022 10:59:00 AM  
**Attachments:** [CBER Comments on draft-spikevax-labeling-text-pi-clean 1.28.22.docx](#)  
[image001.png](#)  
**Importance:** High

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Dear Dr. Olsen:

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. Please review the annotated revised package insert and the requested revisions in the attached word document . Please provide both a tracked changes and clean copy of the revised package insert in your response.

Please submit your response as an amendment to 125752 as soon as possible – but no later than 1:30 PM EST today (Friday, January 28).

Warm regards,

Jo Resnick

**Josephine Resnick, Ph.D**

*Biologist (Primary Reviewer)*

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