

From: [Kulinski, Joseph](#)
To: [Michelle Olsen](#)
Cc: [Agnihothram, Sudhakar](#); [Resnick, Josephine](#)
Subject: STN 125752 - IR #34: Revised SPIKEVAX PPI
Date: Tuesday, December 14, 2021 4:13:00 PM
Attachments: [STN 125752 - draft labeling text - patient info - CBER Revisions 12.14.2021.docx](#)
[STN 125752 - draft labeling text - patient info - CBER Revisions 12.14.2021.pdf](#)
[image001.png](#)

Dear Dr. Olsen:

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. Please review the attached annotated revised "Information for Recipients and Caregivers" document and accept all revisions in the MS word file as you feel appropriate. For changes not accepted and/or for any further revisions, please retain the tracking information and provide the rationale for changes not accepted and for additional edits. Please provide both a tracked changes and clean copy of the revised document in your response.

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125752 at your earliest convenience but no later than December 17, 2021.

Thank you,

Joseph Kulinski, PhD

Biologist / Primary Reviewer

CBER/OVRR/DVRPA

U.S. Food and Drug Administration

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