

From: [Kulinski, Joseph](#)
To: [Michelle Olsen](#)
Cc: [Agnihothram, Sudhakar](#); [Resnick, Josephine](#)
Subject: STN 125752: Information Request #33 / CBER Labeling Revisions
Date: Friday, December 10, 2021 5:35:00 PM
Attachments: [image001.png](#)
[125752 annotated draft labeling text - CBER Comments 12.10.2021.docx](#)
[125752 annotated draft labeling text - CBER Comments 12.10.2021.pdf](#)

Dear Dr. Olsen:

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. Please review the attached annotated revised package insert and accept all revisions in the word document 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 an tracked changes and clean copy of the revised package insert in your response. We also have the following additional comment:

1. Please refer to the following labels:
 - Multiple-dose 5.5 mL (10 dose) vial carton label, NDC 80777-100-99
 - Multiple-Dose 5.5 mL vial container label, NDC 80777-100-11
 - Multiple-Dose 7.5 mL (10 Doses) vial carton label, NDC 80777-100-98
 - Multiple-Dose 7.5 mL vial container label, NDC 80777-100-15

Please change the wording "No Preservative" to "Contains No Presentative" on each of these labels.

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 14, 2021.

Thank you,
Joe

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