

RESPONSE TO FDA COMMENTS ON LABELING DATED NOVEMBER 15, 2021

The Sponsor acknowledges FDA Comments on LABELING (in **BOLD**)

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 comments:

ITEM 1:

- 1. Please note that CBER has designated the proper name for Spikevax to be “COVID-19 Vaccine, mRNA”. Please make the necessary updates throughout your carton & container labels as well as your package insert.**

Sponsor Response

The proper name has been updated on all files as requested.

ITEM 2:

- 2. 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:**
 - a. Please revise the point size and typeface of the proper name and the tradename to ensure they are equal in prominence ((21 CFR 610.62(b)).**
 - b. On the carton labels, please increase the font size of “For 18 years and older.” On the vial labels, please increase the prominence and size of “For 18 years and older” ((21 CFR 610.62(b)).**
 - c. Please clarify the purpose of the “2D datamatrix code encoded P/N” listed on the carton and container labels and what information the 2D datamatrix will encode.**
 - d. Per the Drug Supply Chain Security Act (DSCSA), Product Identifiers must include information in both machine and human readable format. On the carton labels, please add the human readable format to these labels, or specify the location and content of the human readable text to be included at the time of printing. Please also clarify the location of the machine readable graphic.**

Sponsor Response

- a. The point size of the trade name has been reduced to a size that is equal in prominence to the proper name on the vial labels and cartons.
- b. The point size of “For 18 years and older” has been increased on the cartons. On the vial labels, due to space constraints, this statement has been moved to the top of the side panel and bolded to increase prominence.
- c. The 2D datamatrix code encoded P/N on the carton is a code with the part number for the carton artwork version and is scanned by the packaging line equipment to ensure the correct carton is used. The human readable part number will be adjacent to the 2D code and is denoted with the placeholder text “XXXXXX”. The part number will be assigned when the artwork is final. Due to a technical change, the layout of the vial labels has been modified since the original labels were submitted. The 2D datamatrix code for the part number on the vial label has been removed from the left side. The human readable part number will still appear on the left side and is denoted with the placeholder text “XXXXXXXX”. The size of the variable information coding area (black rectangle) on the right side of the label has been increased. See additional information in item d(2) below.
- d. Product identifier requirements are present on the vial labels and cartons. Notes are included on the artwork files in this submission and detailed in this response.
 1. On the back of the cartons, the human readable NDC and GTIN are part of the artwork and printed above the variable coding area (black box). Variable coding information is laser imaged in the black box area on the packaging line. The black box area will contain the expiration date, lot number, and serial number in human readable format. This black box area also will include a 2D datamatrix code encoded with GTIN, expiration date, lot number, and serial number.
 2. On the right side of the vial labels, the NDC number is part of the artwork and printed next to the linear barcode that is encoded with the NDC. Variable coding information is laser imaged in the black rectangle area on the packaging line. The black rectangle area will contain the lot number and expiration date in human readable format. This black rectangle area also will include a 2D datamatrix code encoded with GTIN, expiration date, and lot number.

ITEM 3:

- 3. Please list the storage temperature on the carton and container labels to be consistent with wording in the package insert.**

Sponsor Response

The storage temperatures have been updated to be consistent with the package insert.