

### REQUEST FOR PROPRIETARY NAME REVIEW

<b>Primary Name</b>	Spikevax
<b>Alternate Name</b>	Spykevax
<b>Intended Pronunciation of the Proposed Proprietary Name</b>	SPĪK-văx
<b>Derivation of Proprietary Name</b>	Spikevax is coined from the spike protein of the SARS-CoV-2 virus and vaccine
<b>Intended Meaning of Proprietary Name Modifier (if applicable)</b>	Not applicable
<b>Pharmacologic/Therapeutic Category</b>	Vaccine
<b>Proposed Labeling</b>	Proposed professional and patient labeling are provided in this submission:  <a href="#">Draft Labeling Text-Prescribing Information</a> <a href="#">Draft Labeling Text-Patient Information</a>
<b>Proposed Container Labels and Labeling</b>	Proposed vial labels and cartons are provided in this submission:  <a href="#">Draft Vial Label 5.5 mL</a> <a href="#">Draft Vial Label 7.5 mL</a> <a href="#">Draft Carton 5.5 mL</a> <a href="#">Draft Carton 7.5 mL</a>
<b>Likely Care Environment(s) for Dispensing (e.g., retail pharmacy, hospital pharmacy; specialty pharmacy) and Use (e.g., inpatient, outpatient, LTC, clinic, doctor's office, home)</b>	<u>Dispensing environments</u> During pandemic assume any facility that could be leveraged as an outpatient clinic including doctor's offices, pharmacies, long-term care clinics, municipal health clinics, and public schools. Retail, hospitals, specialty pharmacies.  <u>Use environments</u> See dispensing environments
<b>Delivery system model and instructions</b>	Not applicable
<b>Measuring device (if supplied with product when dispensed)</b>	Not applicable