

**175th Vaccines and Related Biological Products
Advisory Committee (VRBPAC) Meeting June 28, 2022**

DISCUSSION QUESTIONS

Please discuss the various considerations involved in updating the strain composition for COVID-19 vaccines in the U.S. Please provide input on the following and discuss whether any additional data are needed to facilitate a recommendation:

- Is a change to the current COVID-19 vaccine strain composition necessary at this time?**
- Please discuss the evidence supporting:**

1) the selection of a specific Omicron sub-lineage (e.g., BA.1 vs. BA.4/BA.5)

2) a monovalent (Omicron) or bivalent vaccine (prototype + Omicron)

3) extrapolating the available clinical data for modified vaccines to different age ranges

What additional data, if any, would be needed to recommend an updated composition of the primary series vaccine? If the booster vaccine composition changes, would continuing use of the prototype primary series vaccine this fall still be acceptable?