Selection of the 2026-2027 Formula for COVID-19 Vaccines - Introduction

Vaccines and Related Biological Products Advisory Committee
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Purpose of Today's VRBPAC Committee Discussion

- Review SARS-CoV-2 surveillance and epidemiology data, genetic and antigenic characteristics of recent virus isolates, serological responses to current vaccines, and the availability of candidate COVID-19 vaccines (2026-2027 Formula)

- Make recommendations for the composition of the 2026-2027 Formula for COVID-19 vaccines for use in the United States

Agenda Outline

- Introduction
- Update on Current Epidemiology of COVID-19 and SARS-CoV-2 Variants
  - Dr. Natalie J Thornburg, CDC
- Updates on COVID-19 Vaccine Effectiveness
  - Dr. Amanda B Payne, CDC
- WHO TAG-CO-VAC May 2026 Recommendation on Antigen Composition of COVID-19 Vaccines
  - Dr. Bart Haagmans, Department of Viroscience, Erasmus MC, Rotterdam NL – WHO Technical Advisory Group Chair
- Manufacturers Presentations
  - Moderna
  - Pfizer/BioNTech
  - Sanofi
- FDA Considerations and Recommendation for COVID-19 Vaccines (2026-2027 Formula)
  - Dr. Carol Weiss, FDA
- Open Public Hearing
- Additional Q & A
- Committee Discussion and Voting

Summary of the Process Used for the COVID-19 Vaccine Strain Composition

- The Vaccines and Related Biological Products Advisory Committee (VRBPAC) has previously discussed the process and methodology for making a strain composition recommendation for COVID-19 vaccines for the U.S. (April 2022 and January 2023 VRBPAC)
- The committee agreed with the general framework of the process outlined by FDA consisting of the following steps:
  - In collaboration with other U.S. public health agencies, FDA will routinely monitor and review the epidemiology of circulating SARS-CoV-2 variants in the U.S., the effectiveness of available vaccines in use, the available clinical data, the available nonclinical data, and any current vaccine manufacturing issues
  - On a regular basis (at least yearly), FDA and VRBPAC will review the most recent data to determine whether to recommend an updated COVID-19 vaccine for use in the U.S.
    - Goal would be to reassess current vaccines and decide if improvement is needed and could offer benefit
    - The current annual target for review is late spring/early summer, coinciding with the availability of recent vaccine effectiveness data and serology study data from current vaccines
    - A concerning change in the virus landscape or the emergence of a more pathogenic escape virus in the context of a public health emergency would prompt an ad hoc meeting of the VRBPAC
  - FDA reviews the discussions and recommendations put forth by other regulatory groups and public health agencies
  - In technical working group meetings, FDA discusses clinical and nonclinical data generated by manufacturers of U.S.-authorized/approved COVID-19 vaccines and any current manufacturing issues that might impact vaccine availability

Voting Question for the Committee

1. For the 2026-2027 Formula of COVID-19 vaccines in the U.S., does the committee recommend JN.1-lineage XFG variant as the preferred variant for an updated monovalent vaccine?

Please vote “Yes” or “No” or “Abstain”

Discussion Topic for the Committee

- Please discuss circumstances that may warrant recommendation of a non-JN.1 lineage variant (e.g., BA.3.2) for COVID-19 vaccine use in the U.S.


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