Advisory Commission on Childhood Vaccines (ACCV) update

(July 2024 – January 2025)

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VRBPAC meeting

September 20: FDA's VRBPAC met to discuss considerations related to the use of pertussis Controlled Human Infection Models (CHIMs) in pivotal studies to demonstrate efficacy of pertussis vaccines for the purpose of licensure.

The discussion topics were the following:

- Controlled human infection model
- Colonization Model

VRBPAC meeting

October 10 : FDA's VRBPAC met to publicly discuss and make recommendations on the strain selection for the influenza virus vaccines for the 2025 southern hemisphere influenza season. Under Topic II, the committee discussed pandemic preparedness for highly pathogenic avian influenza virus including considerations for vaccine composition for (H5) vaccines.

The discussion topics were the following:

- Please discuss and provide input on the proposed strain change process during the inter-pandemic period.
- Please discuss whether a change to the current composition of a licensed prototype vaccine using this process is needed for preparedness purposes and whether candidate vaccine viruses are available that are appropriate for an update to licensed prototype vaccines

VRBPAC meeting

December 12: FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss Considerations for Respiratory Syncytial Virus [RSV] Vaccine Safety in Pediatric Populations.

The discussion topics were the following:

- RSV Vaccine Safety in Pediatric Populations

- Sequential Administration of RSV Monoclonal Antibodies (mAbs) followed by RSV Vaccines in Infants and Toddlers

Influenza Strain Update Approvals

- **FLUAD (Influenza)** by Seqirus on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **FluLaval (Influenza)** by GlaxoSmithKline on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **Flublok (Influenza)** by Protein Sciences on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **Flucelvax (Influenza)** by Seqirus on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **Fluzone (Influenza)** by Sanofi Pasteur on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **Fluarix (Influenza)** by GlaxoSmithKline on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza
- **Afluria (Influenza)** by Seqirus on 01 July, 2024 to include the 2024-2025 United States formulation and associated labeling revisions for seasonal influenza

Bexsero

- **19 August:** FDA approved GlaxoSmithKline's Efficacy Supplement for Meningococcal Group B Vaccine (BEXSERO) for use in individuals 10 through 25 years of age that included a revision to the *accelerated approval* of a two-dose schedule administered at 0 and ≥1 month to the "*traditional" approval* of a two-dose schedule administered at 0 and 6 months and a three-dose schedule administered at 0, 1-2, and 6 months.

COVID-19 Strain Updates

- **22 August:** FDA approved **SPIKEVAX (COVID-19 vaccine, mRNA)** by Moderna on 22 August, 2024 to include the use of 2024-2025 Formula in individuals 12 years of age and older with associated labeling revisions.

- **22 August:** FDA approved ·**COMIRNATY (COVID-19 vaccine, mRNA)** by Pfizer on 22 August, 2024 to include the use of 2024-2025 Formula in individuals 12 years of age and older with associated labeling revisions.

- **30 August:** FDA authorized **Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula)** by Novavax on 30 August 2024 to include the use of 2024-2025 Formula in individuals 12 years of age and older

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

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Questions?

The opinions expressed herein – *especially in response to questions* – are an informal communication and represent my best judgment. These comments/responses do not bind or obligate FDA.