# Advisory Commission on Childhood Vaccines (ACCV)

## Food and Drug Administration Update

## September 2, 2021

**CDR Valerie Marshall, MPH, PMP, GWCPM**
**Immediate Office of the Director**
**Office of Vaccines Research and Review (OVRR)**
**Center for Biologics Evaluation and Research (CBER)**
**Food and Drug Administration (FDA)**

# FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals

- On August 12, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow **an additional dose** in certain immunocompromised individuals, specifically for
  - Solid organ transplant recipients or
  - Those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- The authorizations for these vaccines have been amended to allow for an additional, or third, dose to be administered **at least 28 days following the two-dose regimen of the same vaccine**
- The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:
  - Pfizer-BioNTech: aged ≥ 12 years
  - Moderna: aged ≥ 18 years

# Approval of First COVID-19 Vaccine

- On August 23, 2021, the FDA approved the first COVID-19 vaccine.
- The Pfizer-BioNTech COVID-19 Vaccine will be marketed as **Comirnaty™**, for the prevention of COVID-19 disease in individuals 16 years of age and older.
- The vaccine also continues to be available under emergency use authorization (EUA) for
  - Individuals 12 through 15 years of age and
  - A third dose in certain immunocompromised individuals.

# Tick-Borne Encephalitis (TBE) Vaccine

- On August 13, the FDA approved TICOVAC™ for active immunization to prevent tick-borne encephalitis (TBE) in individuals one year of age and older
- TBE is a viral infection of the brain and spine, which can be transmitted to humans through the bite of an infected tick.
- Although TBE is not endemic in the U.S., to date, it has been identified in more than 35 countries across Europe and Asia.
- US citizens, such as members of the US military deployed to endemic regions and travelers to those regions who engage in warm weather outdoor activities, are at risk for TBE.

# Expansion of Shingrix™

- On July 23, FDA approved a supplement to the biologics license application for Zoster Vaccine, Recombinant, Adjuvanted (Shingrix)
  - To expand the indication to include the prevention of herpes zoster (HZ) (shingles) in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy

# FDA Websites

- **5 Things You Need to Know about the COVID-19 Vaccine for Adolescents 12 through 17**
  - **https://www.fda.gov/consumers/consumer-updates/5-things-you-need-know-about-covid-19-vaccine-adolescents-12-through-17**
- **Vaccine Development 101**
  - https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101
- **Emergency Use Authorization for Vaccines Explained**
  - https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

# Thank you!