

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

New Approval

Ervebo – Ebola Virus Vaccine

- In December 2019, the FDA approved Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), caused by Zaire ebolavirus in individuals 18 years of age and older.
 - Ervebo is administered as a single-dose injection, and is a live, attenuated vaccine that has been genetically engineered to contain a protein from the Zaire.
 - While the risk of Ebola virus disease in the U.S. remains low, the U.S. government remains committed to fighting devastating Ebola outbreaks in Africa, including the current outbreak in the Democratic Republic of the Congo.
 - This approval is an important step in continuing efforts to fight Ebola in close coordination with partners across HHS, as well as our international partners, such as the World Health Organization.

Fluzone Quadrivalent – High Dose

- In November 2019, FDA approved a supplement to the Biologics License Application for Fluzone to include the High Dose Quadrivalent formulation for persons 65 years of age and older for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

Menveo – Booster Dose

- In December 2019, the FDA approved a supplement to the BLA for Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (Menveo) to include safety and immunogenicity data to support revaccination of adolescent and adults.
 - A single booster dose of MENVEO may be administered to individuals aged 15 through 55 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

Coronavirus Outbreak

- The FDA is collaborating with interagency partners, product developers, international partners and global regulators to expedite the development and availability of medical products needed to diagnose, treat, mitigate and prevent such outbreaks.
- As part of FDA's ongoing commitment to prepare and respond to infectious disease outbreaks, the agency is sharing updates on processes in place to help developers understand the pathways, including Emergency Use Authorization (EUA), that may be available to more rapidly advance and make medical countermeasures available for this virus.



Thank you!

