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 Vaccine Approval - VAXELIS

- In December 2018, the FDA approved Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine (VAXELIS)
  - VAXELIS is indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzae (H. influenzae) type b.
  - VAXELIS is approved for use as a 3 dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

Ixario (Japanese Encephalitis Vaccine, Inactivated, Adsorbed)

- In October 2018, the FDA approved a supplement to the biologics license application for Ixario to:
  - i) include an alternate primary immunization series of two 0.5 mL doses of IXIARO administered at 7 days apart for individuals 18 through 65 years of age, and
  - ii) update the IXIARO package insert to include data to support the concomitant use of IXIARO primary immunization series, two 0.5 mL doses administered 28 days apart, with U.S.-licensed rabies vaccine (RabAvert®) administered for pre-exposure prophylaxis.

Fluzone Quadrivalent

- In February 2019, FDA approved a supplement to the biologics application for Fluzone Quadrivalent to include the 2019 Southern Hemisphere formulation and associated labeling revisions.

Vaccines and Related Biological Products Advisory Committee

- On March 6, 2019, the Center for Biologics Evaluation and Research's (CBER) VRBPAC met in an open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season.

- On March 7, 2019, the committee met in open session to discuss and make recommendations on the safety and effectiveness of Dengue Tetravalent Vaccine (Live, Attenuated) (DENGVAXIA) manufactured by Sanofi Pasteur.

Thank you!


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