

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

December 2, 2016



CDR Valerie Marshall, MPH

Immediate Office of the Director

Office of Vaccines Research and Review (OVRR)

Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration (FDA)



Outline

- **Vaccine Supplement Approvals**
- **Noteworthy FDA Publications**



Vaccine Supplement Approvals

Daptacel

[Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed]

- In September 2016, the FDA approved a supplement to the biologics license application (BLA) for Daptacel to include immunogenicity and safety data to support the co-administration of Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) with a fifth dose of Daptacel in children 4 through 6 years of age.

Q-Pan

[Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted]

- In September 2016, FDA approved a supplement to the biologics license application (BLA) for Q-Pan to extend the age range of the vaccine to include persons **6 months through 17 years of age** at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.
- The vaccine was previously approved for use in persons **18 years of age and older**



Noteworthy FDA Publications

FDA Publication

- **Human antibody repertoire following VSV-Ebola vaccination identifies novel targets and virus neutralizing IgM antibodies.**

Surender Khurana, Sandra Fuentes, Elizabeth M. *et al.*
Nature Medicine; Published October 2016

- Scientists at the FDA have demonstrated novel immune system targets on Ebola virus and identified the major type of vaccine-triggered antibodies that neutralize the virus.
- The findings also demonstrate that selection of the appropriate assay may be important for evaluating effective vaccines against the Ebola virus.

FDA Publication

- **Zika (PRVABC59) Infection Is Associated with T cell Infiltration and Neurodegeneration in CNS of Immunocompetent Neonatal C57Bl/6 Mice.**

Mohanraj Manangeeswaran, Derek D. C. Ireland, Daniela Verthelyi; *PLoS Pathogens*. Published November 2016

- A new mouse model developed by scientists at the U.S. Food and Drug Administration may help in exploring the potential activity of Zika virus vaccines and therapeutics.
- The publication describes the a neonatal mouse model that provides a platform for potentially improving and expediting studies to understand the causes and effects (pathology) of the Zika virus.