Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

LCDR 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)

Vaccine Approvals

Prevnar 13 (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed])

- **BLA Supplement Approved: May 22, 2015**
  - To update the package insert to include data from the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) confirmatory efficacy study in adults.
  - The study demonstrated that Prevnar 13 prevented a first episode of vaccine-type community-acquired pneumonia (CAP) in adults 65 years of age and older.

Licensed Seasonal Influenza Vaccines

- **BLA Supplements Approved: June and July 2015**
  - To include the 2015-2016 influenza formulation
  - FDA's Vaccines and Related Biological Products Committee recommended that the trivalent formulation for the U.S. 2015-2016 influenza season contain the following:
    - an A/California/7/2009 (H1N1)-like virus
    - an A/Switzerland/9715293/2013 (H3N2)-like virus
    - a B/Phuket/3073/2013-like virus
    - The committee also recommended that quadrivalent influenza vaccines contain the above three strains and the following additional B strain:
    - a B/Brisbane/60/2008-like virus

Upcoming Meetings

Advisory Committee Meeting

- On September 15, 2015, the Vaccines and Related Biological Products Committee (VRBPAC) will meet in open session to discuss and make recommendations on the safety and immunogenicity of Seasonal Trivalent Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59 (FLUAD) manufactured by Novartis.