Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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Outline

- Recent Approvals
- Advisory Committee Meeting
- Publications

Recent Noteworthy Vaccine Supplement Approvals

Human Papillomavirus 9-valent Vaccine, Recombinant, Gardasil 9

- In December 2015, the FDA approved a supplement to the biologics license application (BLA) for Human Papillomavirus 9-valent Vaccine, Recombinant, to extend the indication by including **boys and men 16 through 26 years of age** for the prevention of the following diseases:
  - Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
  - Genital warts (condyloma acuminata) caused by HPV types 6 and 11.
- And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33,45, 52, and 58:
  - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

*Human Papillomavirus 9-valent Vaccine, Recombinant was previously indicated in boys **9 through 15 years** of age for the prevention of the same diseases.*

Haemophilus b Conjugate Vaccine (Hiberix)

- In January 2016, FDA approved a supplement to the BLA for Haemophilus b Conjugate Vaccine (Hiberix) to include safety and effectiveness data to support the use of Hiberix for active immunization for the prevention of invasive disease caused by Haemophilus influenza type b in children ***6 weeks to 14 months*** of age for the primary series.

*Hiberix was previously licensed for use as the booster (final) dose of the Hib vaccine series for children a**ged 15 months through 4 years** who previously received the primary series of Hib vaccination*.

Advisory Committee Meetings

Advisory Committee Meeting

- On November 13, 2015, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss considerations for evaluation of the safety and effectiveness of vaccines administered to pregnant women to protect the infant.
  - VRBPAC discussed that serological markers may be acceptable to infer vaccine effectiveness to protect the infant from disease.
  - Furthermore, the duration and type of safety follow-up of the infant as well as safety assessments in the mother will depend on the vaccine under investigation and disease targeted.
  - The committee noted the challenges with safety follow-up in infants, as infants are seen by different providers.
  - Also, the need for clinical studies to assess potential immune interference with childhood vaccines depends on the vaccine antigen used for maternal immunization.

Influenza Strain Selections

- On March 4, 2016, the VRBPAC committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2016-2017 influenza season.