



Update to the NVAC Committee

New Approval

- In November 2015, the Food and Drug Administration (FDA) approved Influenza Vaccine, Adjuvanted, Fludax, the first seasonal influenza vaccine containing an adjuvant. Fludax, a trivalent vaccine produced from three influenza virus strains (two subtypes A and one type B), is approved for the prevention of seasonal influenza in people 65 years of age and older.

Noteworthy Supplement Approvals

- In September 2015, FDA approved a supplement to the BLA for Hepatitis B Vaccine, Recombinant (Engerix-B) to include safety and immunogenicity data for adults with type 2 diabetes mellitus in the Engerix-B Package Insert Prescribing Information.
- In November 2015, FDA approved a supplement to the biologics license application (BLA) for Anthrax Vaccine Adsorbed (BioThrax) to include post-exposure prophylaxis (PEP) of disease resulting from suspected or confirmed *Bacillus anthracis* exposure, when combined with the recommended course of antimicrobial therapy for persons 18 through 65 years of age.
- In December 2015, the FDA approved a supplement to the 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.

- 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 aged 15 months through 4 years who previously received the primary series of Hib vaccination.

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



Advisory Committee Meetings

- 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.
- 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.