



Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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Office of Vaccines Research and Review (OVRR)

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Food and Drug Administration (FDA)



Outline

- **Recent Approvals**
- **Advisory Committee Meeting**
- **Publications**



Recent Vaccine Supplement Approvals

BioThrax, Anthrax Vaccine Adsorbed

- Supplement approved in November 2015
- 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
- Age: Persons 18 through 65 years of age

Engerix-B Hepatitis B Vaccine (Recombinant)

- Supplement approved September 2015
- To include safety and immunogenicity data for adults with type 2 diabetes mellitus in the Engerix-B Package Insert Prescribing Information.



Advisory Committee Meeting

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.

Briefing Document:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM471661.pdf>



Publications

Recent Publications

- **Comparison of three whole-cell pertussis vaccines in the baboon model of pertussis.**
 - Clin Vaccine Immunol 2015 Nov 11; Warfel JM, Zimmerman LI, Merkel TJ
- **Human complement bactericidal responses to a group A meningococcal conjugate vaccine in Africans and comparison to responses measured by 2 other group A immunoassays.**
 - Clin Infect Dis 2015 Nov 15;61 Suppl 5:S554-62