



Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

June 2016

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Outline

- **Recent Noteworthy Approvals**
- **Emergency Preparedness**
- **Publications**



Recent Noteworthy Vaccine Supplement Approvals

Meningococcal Group B Vaccine: Change in Vaccine Schedule

- In April 2016, the FDA approved a supplement to the biologics license application (BLA) for Meningococcal Group B Vaccine (Trumenba®) to include a two-dose schedule (a dose administered at 0 and 6 months) according to the regulations for accelerated approval.
 - The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.
- The approval also included a modification of the three-dose schedule from administration at 0, 2, and 6 months to administration at 0, 1-2, and 6 months.

Labeling: Products not made with Natural Rubber Latex

- In April 2016, the FDA approved BLA supplements to change the product labeling in accordance with the guidance for industry titled, “Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not made with Natural Rubber Latex” for the following vaccines:
 - Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed
 - Hepatitis B Vaccine (Recombinant)
 - Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)
 - Hepatitis A and Hepatitis B (recombinant) Vaccine
 - Rotavirus Vaccine, Live, Oral
 - Human Papillomavirus Bivalent (Types 16 and 18) Vaccine
 - Hepatitis A Vaccine, Inactivated
 - Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine

Updates to the Package Insert: Influenza, Vaccine

- In March 2016, the FDA approved a supplement to the BLA for Influenza Virus Vaccine (Afluria) to include
 - Non-seasonal updates to the package insert (PI) for the 2016/2017 season
 - Update the post-marketing adverse event terms, and
 - Include information related to the Afluria pregnancy exposure and surveillance study in the PI.

Influenza Virus Vaccine (Fluzone® Quadrivalent)

- In March 2016, the FDA approved a supplement to the BLA for Influenza Virus Vaccine (Fluzone® Quadrivalent) to include the 2016 Southern Hemisphere formulation.
 - The influenza strains to be included in 2016 Southern Hemisphere formulation were recommended by WHO for influenza vaccines to be used during the Southern Hemisphere influenza season.



Emergency Preparedness

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- There are no FDA-approved vaccines for Zika virus, nor is the FDA aware of vaccines in advanced development. FDA is prepared to work with industry to clarify regulatory and data requirements necessary to move products forward in development as quickly as possible.
- On June 6 and 7, 2016, FDA is participating in a WHO Consultation on potential regulatory approval pathways for Zika vaccines during the WHO declared Public Health Emergency of International Concern.
- On May 4 and 5, 2016, FDA participated in the 2nd WHO Consultation on Regulatory Considerations for the Evaluation of Ebola Vaccines Intended for Emergency Use.
- On March 24 and 25, 2016, the FDA participated in the WHO consultation on Rationale for a vaccine efficacy trial during Public Health Emergencies: Integrating infectious disease modeling.