Advisory Commission on Childhood Vaccines (ACCV) update

(December 2022 – February 2023)

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Moderna and Pfizer-BioNTech COVID-19 Vaccines

8 December 2022: Amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent vaccines to include use in children down to 6 months of age.

The Moderna COVID-19 Vaccine, Bivalent is authorized for administration as a single booster dose at least two months following completion of a primary series with the monovalent Moderna COVID-19 Vaccine in children 6 months through 5 years of age.

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration as the third dose of the three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age. Those eligible for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent are children 6 months through 4 years of age who have not yet received the third dose of the three-dose primary series with the monovalent Pfizer-BioNTech COVID-19 Vaccine.

Adacel

9 January: approved Adacel (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed [Tdap]) for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than two months of age.

VRBPAC meetings

26 January: considered whether and how the composition for primary doses of the currently available COVID-19 vaccines should be modified and how and whether the composition and schedule for booster doses should be adjusted moving forward.

VRBPAC meetings

28 February: to discuss and make recommendations on the safety and effectiveness of ABRYSVO (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older.

VRBPAC meetings

1 March: to discuss and make recommendations on the safety and effectiveness of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted), manufactured by GSK, with a requested indication for active immunization for the prevention of LRTD caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older.

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Questions?

The opinions expressed herein – *especially in response to questions* – are an informal communication and represent my best judgment. These comments/responses do not bind or obligate FDA.