Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19 for Use in Pediatric Populations

Vaccines and Related Biological Products
Advisory Committee meeting (June 10, 2021)

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Introduction

- The SARS-CoV-2 pandemic continues in the U.S. and world-wide
- SARS-CoV-2 pandemic has affected individuals of all ages in the U.S.
  - Although incidence and severity of disease are generally lower in pediatric populations compared with adults, severe COVID-19 cases resulting in hospitalization or death have occurred in pediatric populations.
- COVID-19 vaccination is an important public health measure to control SARS-CoV-2
- There is intense interest in pediatric COVID-19 vaccines

Biologics License Application

- Section 351 of the Public Health Service Act, 42 USC 262:
  …a biologics license application (BLA) can be approved on the basis of a demonstration that –
  - the biological product … is **safe, pure, and potent**; and
  - the facility … meets standards designed to assure that the biological product continues to be safe, pure, and potent; ….

- FDA Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19 (June 2020)
  - Describes the data needed to facilitate clinical development and licensure of vaccines to prevent COVID-19
  - Provides an overview of key considerations to satisfy regulatory requirements
  - Efficacy of COVID-19 vaccines should be demonstrated in **adequate and well-controlled clinical trials** that directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.
  - Safety evaluations … size of the database required to support licensure

Emergency Use Authorization

- FDA may issue an Emergency Use Authorization (EUA) only after several statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-2))
- Issuance of an EUA requires a determination that the known and potential benefits of the **investigational** product outweigh its known and potential risks based on data from at least one well-controlled Phase 3 clinical trial demonstrating vaccine's safety and efficacy in a clear and compelling manner
- Issuance of an EUA for an investigational COVID-19 vaccine would require adequate manufacturing information
- FDA Guidance for Industry:
  Emergency Use Authorization for Vaccines to Prevent COVID-19
  - Describes the agency's current recommendations regarding the data needed to support issuance of an EUA for vaccines to prevent COVID-19
  - Reflects advice the FDA has been providing to vaccine developers

Previous VRBPAC Meetings to Discuss COVID-19 Vaccines

October 22, 2020:

The development, authorization, and/or licensure of COVID-19 vaccines (in general)

December 10, 2020:

To discuss the EUA request of the Pfizer-BioNTech COVID-19 Vaccine

December 17, 2020:

To discuss the EUA request of the Moderna COVID-19 Vaccine

February 26, 2021:

To discuss the EUA request of the Janssen COVID-19 Vaccine

COVID-19 Vaccines Available for Use under EUA

Sponsor	Regimen	Indicated Population
Pfizer-BioNTech	2 doses	Individuals ≥12 years of age
Moderna	2 doses	Adults ≥18 years of age
Janssen	Single dose	Adults ≥18 years of age

Overview of Today's Agenda

- **FDA Introduction**
  - Ramachandra Naik, Ph.D.
- **CDC: Epidemiology of COVID-19 in the Pediatric Populations**
  - LCDR Hannah Kirking, M.D., Medical Epidemiologist, Division of Viral Diseases, Respiratory Viruses Branch
- **CDC: Operational Aspects**
  - Shannon Stokley, DrPH, Associate Director for Science, NCIRD
- **Post-Authorization Surveillance Activities**
  - Steven Anderson, Ph.D. Director, Office of Biostatistics and Epidemiology, CBER, FDA
  - CAPT Tom Shimabukuro, M.D., M.P.H., M.B.A., Deputy Director, Immunization Safety Office, CDC
- **Break**

Overview of Today's Agenda (cont.)

- **FDA Presentation – Considerations on Data to Support Licensure and Emergency Use Authorization of COVID-19 Vaccines for Use in Pediatric Populations**
  - Doran Fink, M.D., Ph.D.
- **Additional Q & A Session**
- **Industry Perspective: Considerations for COVID-19 Vaccine Pediatric Trials**
  - Phyllis Arthur, M.B.A. Vice President, Infectious Diseases and Emerging Science Policy, Biotechnology Innovation Organization (BIO), Washington, D.C.
- **Lunch**
- **Open Public Hearing**
- **Break**
- **Committee Discussion and Comments**

Items for Discussion (no vote)

1. Provided there is sufficient evidence of effectiveness to support benefit of a COVID-19 preventive vaccine for pediatric age groups (e.g., 6 to <12 years, 2 to <6 years, and 6 months to <2 years), please discuss the safety data, including database size and duration of follow-up, that would support:
   a. Emergency Use Authorization
   b. Licensure

Items for Discussion (no vote)

2. Provided there is sufficient evidence of effectiveness to support benefit of a COVID-19 preventive vaccine for adolescents 12 to <18 years of age, please discuss the safety data, including database size and duration of follow-up, that would support licensure.

Items for Discussion (no vote)

3. Please discuss studies following licensure and/or issuance of an EUA to further evaluate safety and effectiveness of COVID-19 vaccines in different pediatric age groups.

Thank you!