Advisory Commission on Childhood Vaccines (ACCV)

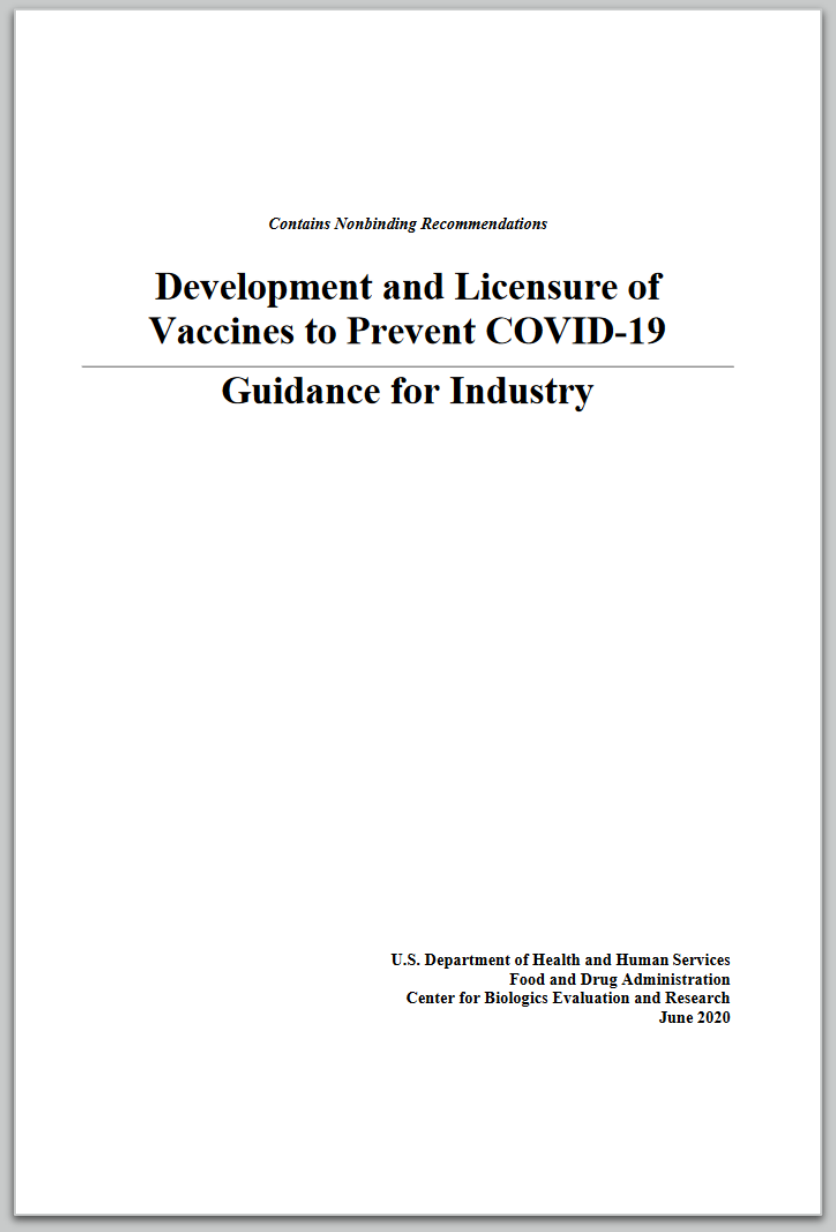
Food and Drug Administration Update

September 4, 2020

CDR Valerie Marshall, MPH, PMP, GWCPM
Immediate Office of the Director
Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Vaccines to Prevent COVID-19

- The FDA is committed to facilitating the development of safe and effective vaccines to prevent COVID-19.
- The Agency released the guidance entitled, “Development and Licensure of Vaccine to Prevent COVID-19.”
- The guidance provides an overview of key considerations to meet requirements for chemistry, manufacturing and control, nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation.



Contains Nonbinding Recommendations

Development and Licensure of Vaccines to Prevent COVID-19

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
June 2020

FDA Advisory Committee Meeting

- On October 22, 2020, the Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet to discuss, in general, the development, authorization and/or licensure of **vaccines to prevent COVID-19**.
- The meeting will be held via an online teleconferencing platform.
- Additional details on how to connect to the meeting can be found at the following website:
  - https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-22-2020-meeting-announcement

Gardasil-9 – New Indication for Head and Neck Cancers

- In June 2020, FDA approved a supplement to the biologics license application for Human Papillomavirus 9-valent Vaccine Recombinant (GARDASIL® 9) to add prevention of oropharyngeal and other head and neck cancers caused by Human Papillomavirus (HPV) types targeted by the vaccine.

Real World Evidence Workshop

- Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines
  - September 17 - 18, 2020
- The purpose of this online symposium is to exchange information with stakeholders from industry, academia, and government about the scientific, clinical, and regulatory challenges and opportunities in using RWE to assess the effectiveness of preventive vaccines.
- Registration: https://www.eventbrite.com/e/real-world-evidence-to-assess-the-effectiveness-of-preventive-vaccines-tickets-110151323574
- **Objectives:**
  - Clarify the FDA's current thinking and the regulatory framework that informs the use of RWE in vaccine development and licensure.
  - Provide context and illustrate the importance of RWE in vaccine development, including through a review of relevant case examples.
  - Discuss emerging infectious diseases (e.g., coronavirus, Ebola, influenza pandemics) and other scenarios (e.g., maternal immunization to prevent disease in infants through the use of licensed/recommended vaccines) in which traditional clinical trials could be impractical or ethically unacceptable.

Thank you!


FDA
U.S. FOOD & DRUG
ADMINISTRATION