Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

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Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)
New Approval
Smallpox and Monkeypox Vaccine

- In September 2019, the FDA approved Jynneos, Smallpox and Monkeypox Vaccine, Live, Non-Replicating for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.
- Although naturally occurring smallpox disease is no longer a global threat, its intentional release of this highly contagious virus could have a devastating effect.
- This approval reflects the U.S. government’s commitment to emergency preparedness.
- The vaccine will be stored in the Strategic National Stockpile.
Vaccines Advisory Committee Meeting

- On November 8, 2019, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss and make recommendations on the development of chikungunya vaccines.

- Chikungunya is a viral disease transmitted to humans by infected mosquitoes. It causes fever and severe joint pain. Other symptoms include muscle pain, headache, nausea, fatigue and rash.

- The committee discussed the feasibility of randomized, controlled clinical disease endpoint efficacy trials, the role of sero-epidemiologic data in identifying an immune marker reasonably likely to predict vaccine effectiveness, and the utility of the non-human primate (NHP) challenge model to assess effectiveness of chikungunya vaccines.
Thank you!