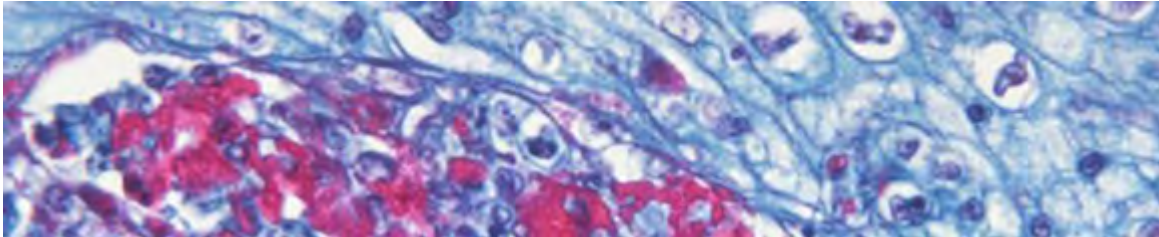




September 25, 2019



FDA approves new live, non-replicating vaccine to prevent smallpox and monkeypox

On September 24, 2019, FDA announced the approval of Jynneos Smallpox and Monkeypox Vaccine, Live, Non-Replicating, for the 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. This is the only currently FDA-approved vaccine for the prevention of monkeypox disease.

Jynneos will be available for those determined to be at high risk of either smallpox or monkeypox infection. This vaccine is also part of the [Strategic National Stockpile \(SNS\)](#), the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency that is severe enough to cause local supplies to be depleted. The availability of this vaccine in the SNS will help ensure that the vaccine is accessible in the U.S. if needed.

With this approval, the FDA issued a material threat medical countermeasure (MCM) priority review voucher to Bavarian Nordic A/S.

[Read the FDA news release](#)

Related links:

- [Approval letter - JYNNEOS \(PDF, 58 KB\)](#)
- [Smallpox Preparedness and Response Updates from FDA](#)
- [21st Century Cures Act: MCM-Related Cures Provisions \(including the MCM priority review voucher program\)](#)
- [Priority Review](#)

[Expanded Access Video Series](#)



FDA has published a new [four-part videos series](#) describing how physicians can submit Expanded Access requests for investigational drugs, including biologics, to FDA, on behalf of a patient. The videos detail the administrative requirements for IND submission, including documentation from the sponsoring drug company, completion of FDA Form 3926, and Institutional Review Board (IRB) approval.

[Expanded Access](#) is a potential pathway for a patient with a serious condition or disease to gain access to an investigational medical product outside of the clinical trial setting when no comparable options exist. [Video transcripts](#) are also available.

Are you prepared?



September is [National Preparedness Month](#). While FDA and other agencies work hard every day to help prepare the nation for potential threats, everyone can be involved in disaster readiness. Learn [what you can do now](#), including precautions for storing water and ensuring the safety of food and medical supplies for your family and pets during and after heavy rain, possible flooding and power outages.

Events

- **October 3, 2019:** [Developing Real-World Data and Evidence to Support Regulatory Decision-Making](#) (Washington, DC) - Through extensive engagement with the stakeholder community, FDA published a [framework](#) (PDF) for the Agency's RWE Program in December 2018. This conference will bring together leading experts to discuss questions about and topics addressed in the framework, as well as emerging topics in the development of real-world data and evidence.
 - **October 9, 2019:** [Vaccines and Related Biological Products Advisory Committee](#) (Silver Spring, MD and [webcast](#)) - The committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2020 southern hemisphere influenza season.
 - **October 16-17, 2019:** [Regulatory Education for Industry \(REdI\): Pharmaceutical Quality Symposium](#) (College Park, MD and [webcast](#)) - FDA will discuss the latest developments in pharmaceutical quality and provide case studies that illustrate the most effective ways to address quality issues and interact with the agency.
 - **November 8, 2019:** [Vaccines and Related Biological Products Advisory Committee public meeting](#) (Silver Spring, MD and [webcast](#)) - The committee will discuss and make recommendations on the development of chikungunya vaccines.
 - **November 12-14, 2019:** [Regulatory Education for Industry \(REdI\): Clinical Investigator Training Course](#) (College Park, MD) This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator responsibilities, understanding the investigator brochure, and FDA requirements across Centers. Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products. Registration is now open.
 - **New! November 18, 2019:** [Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making Public Workshop](#) (Silver Spring, MD and [webcast](#)) - To discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions. [Register](#) by **November 8, 2019**.
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Information for industry

- **Reminder:** On **October 16, 2019**, 12:00 - 1:30 p.m. ET, FDA will host a [webinar for stakeholders](#) interested in learning more about the final guidance [Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions](#) , published on August 29, 2019.
 - Final guidance - [The Special 510\(k\) Program](#) - To describe an optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed device, and design control procedures produce reliable results that can form, in addition to other 510(k) content requirements, the basis for substantial equivalence. This guidance clarifies the types of technological changes appropriate for review as Special 510(k)s. (*September 12, 2019*)
 - Draft guidance - [Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products](#) - Provides guidance to sponsors and applicants on interacting with the FDA on complex innovative trial design (CID) proposals for drugs or biological products. FDA is issuing this guidance to satisfy, in part, a mandate under section 3021 of the 21st Century Cures Act (Cures Act). In accordance with the Cures Act mandate, this guidance discusses the use of novel trial designs in the development and regulatory review of drugs and biological products, how sponsors may obtain feedback on technical issues related to modeling and simulation, and the types of quantitative and qualitative information that should be submitted for review. Comment by **December 23, 2019**. (*September 20, 2019*)
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In case you missed it

- On September 19, 2019, the President signed an [Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health](#). FDA's work to facilitate development of more effective cell lines that can be better scaled through [advanced manufacturing technologies](#) are one example of our commitment to fight flu. The flu vaccine remains one of the most effective and safest ways to protect you and others from the flu and serious flu-related complications. We strongly support these efforts to continue advancing [work to modernize flu vaccine production](#).
- FDA announced two new innovation challenges on device sterilization. Submissions for both are due **October 15, 2019**.
 - [FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies](#) - The goal of this challenge is to identify safe and effective sterilization methods or technologies for medical devices that do not rely on ethylene oxide.
 - [FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions](#) - The goal of this challenge is to develop strategies or technologies to reduce emissions to as close to zero as possible from the ethylene oxide sterilization process.
- On September 19, 2019, FDA [launched](#) an updated version of the [Food Defense Plan Builder \(FDPB\)](#) to help companies meet the requirements of the [Intentional Adulteration](#) rule under the FDA Food Safety Modernization Act (FSMA). FDA will hold a [webinar](#) to provide stakeholders with a brief demonstration of the FDPB v. 2.0 and offer a question and answer session about the tool on **October 10, 2019** at 1:00 p.m. ET.
- From the National Association of County & City Health Officials (NACCHO) - Disasters and emergencies expose the fault lines in our nation's health security. Submit an abstract for the 2020 [Preparedness Summit](#), Fixing Our Fault Lines: Addressing Systemic Vulnerabilities, and contribute strategies, best practices, and tools for addressing systemic vulnerabilities to create more prepared and resilient communities. [Abstracts](#) are due **September 30, 2019 (deadline extended)**.
- From HHS/ASPR - [BARDA Industry Day](#) will be **October 15-16, 2019**. [Registration](#) is open. **New:** Can't make it to D.C.? BARDA's Accelerator Network will be hosting [Hybrid Events](#) so you can watch the general sessions.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.

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