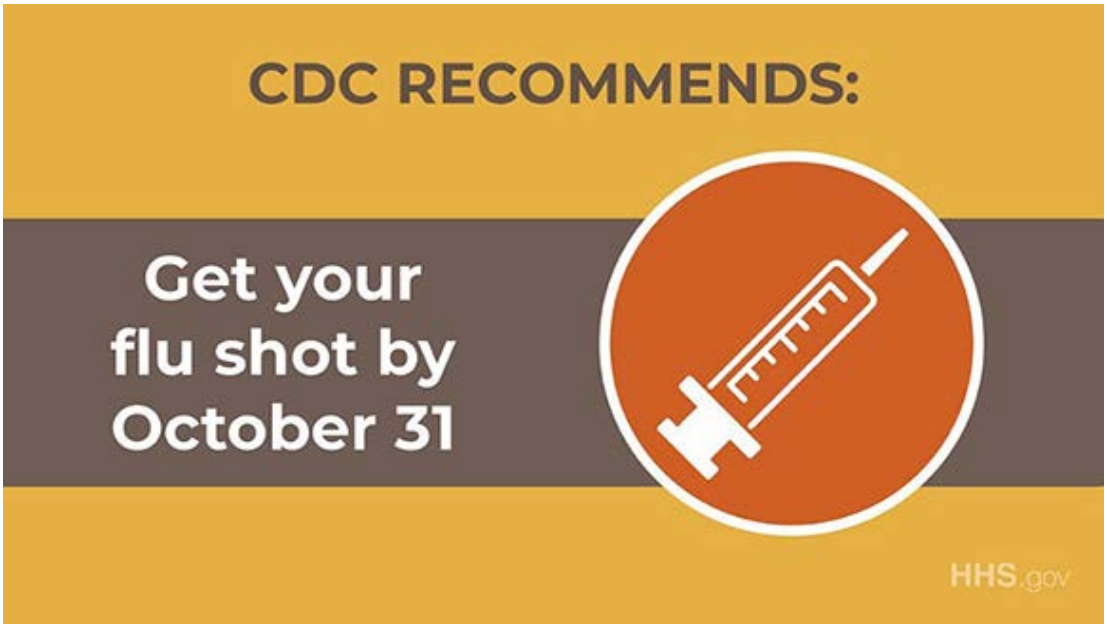
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

October 31, 2018

FDA approves new drug to treat influenza

Yearly vaccination still the best way to prevent and control flu outbreaks



On October 24, 2018, FDA **approved** Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated influenza (flu) in patients 12 years of age and older who have been symptomatic for no more than 48 hours. This is the first new antiviral flu treatment with a novel mechanism of action approved by the FDA in nearly 20 years.

Flu season is already well underway. The U.S. Centers for Disease Control and Prevention (CDC) recommends getting vaccinated by the end of October, as seasonal flu vaccine is one of the most effective and safest ways to protect yourself, your family and your community from the flu and serious flu-related complications, which can result in hospitalizations.

Related links:

- Xofluza product label (PDF, 594 KB)
- Influenza (Flu) Antiviral Drugs and Related Information
- About Flu (from CDC)
- Find a vaccine near you (from HHS)

FDA proposes updated cybersecurity recommendations

To help ensure device manufacturers are adequately addressing evolving cybersecurity threats

On October 17, 2018, FDA issued a draft guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (PDF, 604 KB), which provides updated recommendations to industry on cybersecurity considerations for device design, labeling and documentation that the FDA recommends be included in premarket submissions for medical devices with cybersecurity risk.

FDA will host a public workshop **January 29-30, 2019** to discuss this guidance.

Related links:

- FDA In Brief: FDA proposes updated cybersecurity recommendations to help ensure device manufacturers are adequately addressing evolving cybersecurity threats
- FDA and DHS increase coordination of responses to medical device cybersecurity threats under new partnership; a part of the two agencies' broader effort to protect patient safety *(October 16, 2018)*

Events

- **November 8, 2018:** Vaccines and Related Biological Products Advisory Committee meeting (Silver Spring, MD and webcast) - The Committee will meet in open session to hear an overview of the research program in the Laboratory of DNA Viruses (LDV), Division of Viral Products (DVP), Office of Vaccines Research and Review (OVRR), CBER, FDA.
- **November 8, 2018:** Webinar - Special 510(k) Program Pilot, 3:00 - 4:30 p.m. ET - The Special 510(k) Program Pilot aims to simplify how manufacturers submit certain 510(k)s. All Special 510(k)s received on or after October 1, 2018 will be included in the Special 510(k) Program Pilot.
- **November 13-15, 2018:** Clinical Investigator Training Course (Silver Spring, MD) - Experts from FDA, the University of Maryland, and the University of Pennsylvania will provide training in all aspects of clinical studies: preclinical and clinical science, statistical structure of trials, ethical requirements, and regulatory considerations. Registration closes on **November 6, 2018**, or when registration is full.
- **New! November 19, 2018:** Leveraging Real-World Treatment Experience from Expanded Access Protocols (Silver Spring, MD), hosted by the Reagan-Udall Foundation for the FDA - Building on the Reagan-Udall Foundation for the FDA's work with FDA and other stakeholders to develop the Expanded Access Navigator, this meeting will convene stakeholders from government, industry, academia, and patient groups to discuss Expanded Access process issues. Register to attend.
- **November 27, 2018:** Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions public meeting (Washington, DC and webcast) - This meeting will give stakeholders the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. To attend in-person, register by **November 21, 2018.**
- **New! November 27-28, 2018:** Readiness for Microbial Threats 2030: Exploring Lessons Learned Since the 1918 Influenza Pandemic - A Workshop (Washington, DC), hosted by the National Academies of Sciences, Engineering, and Medicine - The workshop will focus on overcoming the structural and behavioral obstacles to achieving greater preparedness, in order to identify immediate and short-term actions that will have the greatest impact on global health security by 2030.
- **New! November 29-30, 2018:** Pathogen Reduction Technologies for Blood Safety public workshop (Silver Spring, MD and webcast) - to foster the development and implementation of pathogen

reduction technologies for blood components intended for transfusion. Register by **November 8, 2018**.

Information for industry

- FDA issued a draft guidance, Considerations for the Development of Dried Plasma Products Intended for Transfusion (PDF, 104 KB). Once finalized, this guidance will provide recommendations to assist manufacturers in the development of dried plasma products, including recommendations regarding starting materials for the preparation of dried plasma products, manufacturing and product quality, product characterization studies, packaging and reconstitution, clinical studies and devices for manufacturing dried plasma. Comment by **January 28, 2019.**

  This draft guidance builds on recent steps the FDA has taken to advance the development and availability of medical products to help save the lives of American military personnel, through work with the U.S. Department of Defense. *Also see: FDA In Brief: FDA issues draft guidance on the development of dried plasma products intended for transfusion (October 29,2018)*

- FDA has published a table of surrogate endpoints that were the basis of drug approval or licensure. This table, which is available as a downloadable spreadsheet, provides valuable information for drug developers on endpoints that may be considered and discussed with FDA for individual development programs. This table also fulfills a 21st Century Cures Act requirement to publish a list of "surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or a biological product" under both accelerated and traditional approval pathways. Comment by **December 31, 2018**. *(October 30, 2018)*

More: MCM-Related Guidance by Date

In case you missed it

- The U.S. Government released the U.S. Health Security National Action Plan: Strengthening Implementation of the International Health Regulations (PDF, 2.1 MB), containing hundreds of cross-sectoral activities to better prepare the U.S. to prevent, detect, and respond to public health emergencies.
- Remarks by Anna Abram to NC BIO's Annual Meeting 2018, including a section on preparedness *(October 4, 2018)*
- 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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