U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

March 14, 2018

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FDA warns of fraudulent and unapproved flu products

As part of FDA's ongoing efforts to protect consumers from health fraud, the agency is reminding consumers to be wary of unapproved products claiming to prevent, treat or cure influenza, or flu. This year's severe flu season raises new concerns about the potential for consumers to be lured into buying unproven flu treatments, and even worse, buying counterfeit antivirals online from websites that appear to be legitimate online pharmacies.

Consumers should be aware that there are no legally marketed over-the-counter (OTC) drugs to prevent or cure the flu. However, there are legal OTC products to reduce fever and to relieve muscle aches, congestion and other symptoms typically associated with the flu. Products sold online are fraudulent if they claim to prevent, treat or cure the flu, and have not been evaluated by the FDA for that intended use.

These flu claims may indicate that an OTC product is fraudulent:

- reduces severity and length of the flu
- boosts your immunity naturally without a flu shot
- safe and effective alternative to the flu vaccine
- prevents catching the flu
- effective treatment for the flu
- faster recovery from the flu
- supports your body's natural immune defenses to fight off the flu

Read the full press announcement *(March 2, 2018)*

Related links:

- FDA encourages health care professionals and consumers to report adverse reactions to the agency's MedWatch program
- How to buy medicines safely from an online pharmacy
- Seasonal influenza updates from CDC, including prevention, treatment, and flu activity by location

EUA updates

EUA amendments

- March 8, 2018: In response to Hologic, Inc.'s request, FDA concurred (PDF, 130 KB) with the request to add processed whole blood K2EDTA as an authorized

specimen under the EUA of the Aptima Zika Virus Assay issued on June 17, 2016. *Additional information, including updated fact sheets*

- March 6, 2018: In response to CDC's request, FDA concurred (PDF, 85 KB) with an amendment to the Rafa Atropine Auto-Injector EUA for a change to a Rafa-planned manufacturing process. The Rafa Atropine Auto-Injector was initially authorized for emergency use for initial treatment of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning in April 2017. *Additional information*

Reminder:
Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov, in addition to reporting concerns to the manufacturer.

Information about Zika EUAs and amendments is available on the FDA Zika virus response updates page. Also see the latest CDC Zika Laboratory Guidance, last updated July 24, 2017.

Submit BAA white papers by March 30, 2018

In February 2018, FDA revised its Broad Agency Announcement (BAA) for research and development to support regulatory science and innovation. Medical countermeasure (MCM)-related research submissions are encouraged under area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health Security. Proposers are encouraged to submit white papers by **March 30, 2018** for current fiscal year awards.

Related links:

- Full BAA PDF (339 KB) - MCM research areas of interest begin on page 19
- MCM-related extramural research from FDA, including current BAA projects
- More MCM-related funding (under Funding opportunities and challenge information)

Events

- **March 19, 2018:** Public workshop - Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data (Silver Spring, MD and webcast) - register by **March 12, 2018** - *Also see Plan for Issuance of Patient-Focused Drug Development Guidance (PDF, 146 KB)*
- **March 19, 2018:** Public workshop - Utilizing Innovative Statistical Methods and Trial Designs in Rare Disease Settings (Silver Spring, MD and webcast) Advance registration required. To view the webcast, register before **5:00 p.m. ET March 18, 2018**.
- **March 20, 2018:** Promoting the Use of Complex Innovative Designs (CID) in Clinical Trials public meeting (Silver Spring, MD and webcast) - to (1) facilitate discussion and information sharing about the use of CID in drug development and regulatory decision making and (2) obtain input from stakeholders about the CID pilot program.
- **New! March 20-21, 2018:** Engaging the Private Sector Health Care System in Building Capacity to

Respond to Threats to the Public's Health and National Security (Washington, DC), hosted by the National Academies of Sciences, Engineering & Medicine (NASEM) - Through this workshop, the committee will bring together public and private sector partners to discuss approaches to aligning healthcare system incentives with the American public's need for a healthcare system that is optimally prepared and scalable to manage acutely ill and injured patients during a disaster, public health emergency, or other mass casualty event.

- **New! March 21-22, 2018:** Joint Meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee (Silver Spring, MD and webcast) - agenda includes an overview of research programs of the Laboratory of Emerging Pathogens, the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents, and the Laboratory of Molecular Virology in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review, FDA Center for Biologics Evaluation and Research (CBER)
- **New! March 22, 2018:** Public Workshop of the Committee on the Use of Elastomeric Respirators in Health Care (Washington, DC), hosted by NASEM - Topics include challenges and opportunities for the use of elastomeric respirators in public health preparedness and emergency response - *Related FDA research: Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness*
- **March 22, 2018:** Patient Engagement in the National Evaluation System for Health Technology (NEST): Lessons Learned and Best Practices (Baltimore, MD), hosted by the University of Maryland and FDA - The workshop will gather lessons learned and best practices for patient engagement in evidence generation (e.g., planning, collection of data and information, analysis, and dissemination).
- **New! April 6, 2018:** FDA and Health Canada Joint Regional Consultation on the ICH public meeting (Silver Spring, MD and webcast) - register by **April 3, 2018** - this meeting is to provide information and receive comments on the current activities of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as well as the upcoming meetings in Kobe, Japan scheduled for June 4-7, 2018
- **New! April 10, 2018:** Webinar for healthcare professionals - An Introduction to Drug Safety Surveillance and the FDA Adverse Event Reporting System, 1:00 p.m. ET - advance registration required
- **April 16, 2018:** Evaluating Inclusion and Exclusion Criteria in Clinical Trials (Washington, DC and webcast) - register by **April 12, 2018**
- **April 17-20, 2018:** Preparedness Summit (Atlanta, GA) - The theme for the conference is Strengthening National Health Security: Mastering Ordinary Responses, Building Resilience for Extraordinary Events. *(fee)*

Information for industry

- FDA issued two draft guidances furthering the agency's implementation of the Drug Supply Chain Security Act (DSCSA), which outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The Standardization of Data and Documentation Practices for Product Tracing draft guidance (PDF, 170 KB) elaborates on the standards for the interoperable exchange of transaction information, transaction history and transaction statements (product tracing information). The Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act draft guidance (PDF, 283 KB - comments due **April 30, 2018**) describes the FDA's interpretation of terms used in the definitions of "suspect" and "illegitimate" products in the DSCSA to help trading partners meet their verification obligations, which include notifying the FDA. *Also see: FDA In Brief: FDA takes steps to enhance drug supply chain security: setting new recommended data standards to identify, trace packages (February 28, 2018)*
- Under the Mutual Recognition Agreement, FDA notified 4 countries (Czech Republic, Greece, Hungary & Romania) that they are recognized, based on quality, of being able to conduct inspections of manufacturing facilities that meet FDA requirements. In November 2017, 8 additional countries were notified. *(March 1, 2018)*
- Reminder: Comment by **March 20, 2018** on draft guidance Material Threat Medical Countermeasure

Priority Review Vouchers (PDF, 174 KB) *Also see: FDA takes steps to spur development of medical countermeasures needed to protect, prepare for emerging threats to public health and national security and 21st Century Cures Act: MCM-Related Cures Provisions*

More: MCM-Related Guidance by Date

In case you missed it

- FDA approves first tests to screen for tickborne parasite in whole blood and plasma to protect the U.S. blood supply - New donor screening tests to help reduce risk of transfusion-transmitted babesiosis *(March 6, 2018)*
- Remarks from FDA Commissioner Scott Gottlieb, MD, as prepared for oral testimony before the U.S. House Committee on Energy and Commerce Subcommittee on Oversight and Investigations hearing "Examining U.S. Public Health Preparedness for and Response Efforts to Seasonal Influenza." *(March 8, 2018)*
- In a series of tweets, FDA Commissioner Scott Gottlieb, MD gives a brief update on shortage of IV saline products, which was exacerbated by flu season, and the impact of Hurricane Maria on the medical product manufacturing sector in Puerto Rico - *also see Drug Shortages (March 8, 2018)*
- From HHS ASPR - Lessons from Fukushima: New guide provides answers to save lives and improve emergency medical response - The Decision Maker's Guide: Medical Planning and Response for a Nuclear Detonation Guide (DMG) is meant for senior operational responders, emergency managers, public health advisors, healthcare officials, government officials, and other policy and decision-makers to assist preparedness and response decision making by providing readily accessible information that quickly describes what to do. The DMG is based on critical scientific and medical aspects of a nuclear incident as well as the response organization and resources anticipated to be required or available during a response. *(March 12, 2018)*

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