

March 29, 2018

[Take our email survey](#)

## FDA approves Leukine for Acute Radiation Syndrome

### Adds to the country's available treatments in the event of radiological or nuclear emergency

On March 29, 2018, the FDA approved use of Leukine (sargramostim) to increase survival in adult and pediatric patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome, or H-ARS).

Myelosuppression occurs when radiation damages the bone marrow. Suppression of the bone marrow blocks the production of blood cells. Leukine can help patients with H-ARS by facilitating recovery of bone marrow cells that develop into white blood cells that help fight off infections.

Leukine was shown to increase survival when administered up to 48 hours after total body irradiation exposure at doses expected to be fatal to 50% of those exposed subjects under conditions of minimal supportive care.

Leukine is the [third FDA-approved medical countermeasure](#) (MCM) that is indicated to increase survival in patients exposed to myelosuppressive doses of radiation. It was approved by FDA based on efficacy studies in animals (under the [Animal Rule](#)), as efficacy studies in humans could not be ethically conducted. Leukine was originally approved in 1991 and was originally indicated to shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML), and subsequently approved for several oncology-related indications.

The most commonly reported side effects associated with Leukine injections are fever, injection site reactions, and shortness of breath.

Other products from a similar pharmacological class and approved for the same indication are:

- Neupogen ([March 2015](#))
- Neulasta (November 2015)

#### Related links:

- [Radiological and nuclear emergency preparedness information from FDA](#) (new resource)
- [Leukine product label](#) (PDF)
- [Radiation Emergencies](#) (additional information about MCMs from FDA)
- [Acute Radiation Syndrome \(ARS\): A Fact Sheet for the Public](#) (from CDC)
- [Acute Radiation Syndrome: A Fact Sheet for Clinicians](#) (CDC)

---

## FDA Blood Supply and Demand Simulation Model Could Help Nation Prepare for Emergencies

FDA has [developed a model](#) that estimates the amount of blood available in the U.S. during both routine conditions and emergencies. It can be valuable for emergency preparedness planning and for responses requiring blood transfusions.



*Image: The amount of blood that is collected and used in different regions of the country varies. The FDA model of the U.S. blood supply enables public health officials to estimate the availability of blood in each region at any given time. This helps minimize disruption and avoid shortages in the blood supply.*

---

## EUA updates

### EUA reissuance

- March 27, 2018: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay - In response to CDC's request, FDA reissued the April 22, 2013, EUA in its entirety with the CDC-requested amendments incorporated. This test is for the presumptive detection of novel influenza A (H7N9) virus in conjunction with the FDA-cleared CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel in real-time RT-PCR (rRT-PCR) assays in patients with signs and symptoms of respiratory infection. [Additional technical information, including updated fact sheets and instructions for use](#)



### 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](mailto: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.

---

## Events

- **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

- **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)*
- **New! May 24, 2018:** [FY 2018 Generic Drug Research Public Workshop](#) (Silver Spring, MD and webcast) - FDA will take information obtained from the public workshop into account in developing fiscal year 2019 regulatory science initiatives. Register by April 24, 2018.
- **New! June 15, 2018:** [2nd NIH-FDA Joint Agency Microbiome Meeting](#) (College Park, MD and webcast) - This meeting will present ongoing microbiome research being undertaken at the NIH and FDA.
- **New! June 25-26, 2018:** [2018 Center for Biologics Evaluation and Research \(CBER\) Research Science Symposium](#) (Silver Spring, MD and webcast) - participants will discuss scientific topics related to the regulation of biologics, and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision-making. Topics include emerging and re-emerging diseases, and new technologies. [Register](#) to attend in-person or online by **June 18, 2018**; early registration recommended because seating and webcast connections are limited.
- **New! August 13-14, 2018:** [Pediatric Medical Device Development public meeting](#) (Silver Spring, MD and webcast), to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations. To attend in-person, register by **3:00 p.m. ET August 6, 2018**.

---

## Information for industry

- Reminder: 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. *Also see: [MCM-related extramural research from FDA](#), including current BAA projects*
- FDA released two guidance documents regarding postmarketing safety reporting requirements (PMSR) for combination products. Combination products are products composed of two or more different types of medical products (drug, device and/or biological product). [Postmarketing Safety Reporting for Combination Products](#) draft guidance ([comment](#) by **June 19, 2018**) - [Compliance Policy for Combination Product Postmarketing Safety Reporting](#) immediately in effect guidance *Also see [FDA In Brief: FDA reinforces postmarketing safety reporting requirements for combination medical products](#) (March 20, 2018)*

**More:** [MCM-Related Guidance by Date](#)

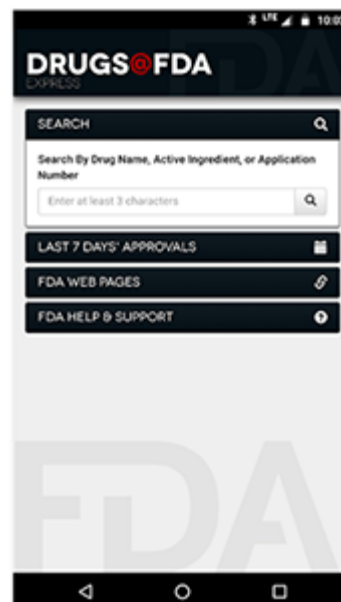
---

## In case you missed it

- **Expiration dating extension update** - FDA is alerting civilian health care professionals and emergency responders of additional AtroPen (atropine) lots that are no longer useable and should be properly disposed of. Please refer to the table on [this page](#) for updates. *(March 23, 2018)*
- **FDA launches mobile app to increase access to information about drugs** - Using the [Drugs@FDA Express](#) mobile app, the

public can search for information about FDA-approved brand and generic prescription and over-the-counter human drugs and biological therapeutic products. (March 22, 2018)

- [Animal Rule Approvals](#) - CDER provides an annual report on CDER-regulated products approved under the Animal Rule. Also see [Animal Rule Information](#)
- FDA Voice - [FDA's New Pilot Program Aims for More Transparency about New Drug Approvals](#) - also see [CDER Clinical Data Summary Pilot Program](#) (March 19, 2018)
- HHS is [soliciting nominations](#) of individuals who are interested in being considered a voting member for appointment to the [Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria](#) - apply by **April 30, 2018**



- From HHS ASPR - [Fighting microscopic threats through international collaboration: Health ministers use lessons learned from the 1918 influenza pandemic to strengthen pandemic preparedness and global health security](#) - One hundred years ago, the 1918 influenza pandemic caused massive devastation, ultimately infecting over 500 million people and killing between 50 and 100 million individuals worldwide. During recent outbreaks of influenza, Ebola, and other emerging infectious diseases, we have learned how critical collaboration among countries and international organizations is for an expedited and more effective response. Working together with our partners to strengthen global health security is crucial to protect Americans from pandemics and other health security threats despite whether they start at home or abroad. (March 19, 2018)
- From NIH - [H7N9 Influenza Vaccine Clinical Trials Begin](#) - H7N9 is an avian influenza virus with pandemic potential. To date, only a few infections in humans have been found, all outside of the United States. However, should the virus change to transmit more easily between people, it could cause widespread suffering: H7N9 has a high mortality rate for a flu virus. To prepare for this possibility, NIAID is sponsoring two new Phase 2 trials of an H7N9 inactivated influenza vaccine, which may provide protection against the virus. The trials, conducted through the [Vaccine and Treatment Evaluation Unit](#) (VTEU) network, will test the vaccines at various doses, with and without adjuvant, and in conjunction with the seasonal influenza vaccine. (March 15, 2018)
- From CDC - [National Outbreak Reporting System](#) (NORS) - A new online tool from CDC lets you search data on outbreaks of intestinal illness spread through food, water, animal contact, person-to-person contact, and more. (March 15, 2018)



Did someone forward you this email? [Subscribe](#)

(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)



Twitter: @FDA\_MCMi  
[www.fda.gov/medicalcountermeasures](http://www.fda.gov/medicalcountermeasures)

U.S. Food and Drug Administration  
10903 New Hampshire Avenue, Silver Spring, MD 20993  
1-888-INFO-FDA (1-888-463-6332)  
[Privacy Policy](#) | [www.fda.gov](http://www.fda.gov)