June 25, 2021

Dear Colleague,

As you and other public health advocates work on the front lines of the COVID-19 pandemic, we want you to know that we recognize your concerns about protecting the safety of yourselves, your families, and others you care for. The FDA's work is critical to ensuring the health and safety of the American public at any time, but is magnified during public health emergencies.

As we address the challenges of the COVID-19 pandemic, protecting the public's health, using science to guide our decisions, and facilitating access to critical medical products continue to be top priorities for the FDA.

Stay up to date on Coronavirus Disease 2019 (COVID-19) by visiting the **Resources for Health Professionals** page.

Updates

- June 24, 2021 - Coronavirus (COVID-19) Update: FDA Authorizes Drug for Treatment of COVID-19
- June 24, 2021 - What Does FDA Regulate? - NEW YouTube Video!
- June 24, 2021 - FDA Advises Consumers Not to Purchase or Use Nitrite "Poppers"
- June 24, 2021 - FDA In Brief: FDA Encourages Inclusion of Patients with Incurable Cancers in Oncology Clinical Trials Regardless of Prior Therapies
- June 23, 2021 - Remarks by Dr. Woodcock at the FDA FY 2021 Generic Drug Science and Research Initiatives Public Workshop
- June 23, 2021 - An Epidemic Continues: Youth Vaping in America
- June 22, 2021 - Coronavirus (COVID-19) Update
- June 21, 2021 - FDA Approves First Oral Blood Thinning Medication for Children

Guidance Documents - Request for Comment

Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings
This guidance provides recommendations to clinical investigators and sponsors regarding the inclusion of patients who have not received available therapy (commonly referred to as existing treatment options) for their cancer in clinical trials of drugs and biological products for the treatment of cancer in the non-curative setting. For the purpose of this guidance, non-curative is generally defined as 1) unresectable, locally advanced, or metastatic disease in solid tumors or 2) hematologic malignancies with unfavorable long-term overall survival.

Submit Comments

Remanufacturing of Medical Devices
This draft guidance is intended to help clarify whether activities performed on devices are likely "remanufacturing." Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements. This draft guidance also includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life. In drafting this guidance, FDA considered objective evidence and information learned from the Agency's activities discussed in this draft guidance.

Submit Comments

Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products
This guidance finalizes the draft guidance, “Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products” dated December 2017, and supersedes the guidance entitled “Guidance for Industry: Changes to an Approved Application: Biological Products” dated 1997 (July 1997 guidance).

Submit Comments

Consumer Updates

Safe Use of Flea and Tick Products in Pets

Flea bites may be more than an itchy annoyance to some dogs and cats. They can cause flea allergy dermatitis — an allergic reaction to proteins in flea saliva. And a pet’s constant scratching can cause permanent hair loss or other skin problems. In

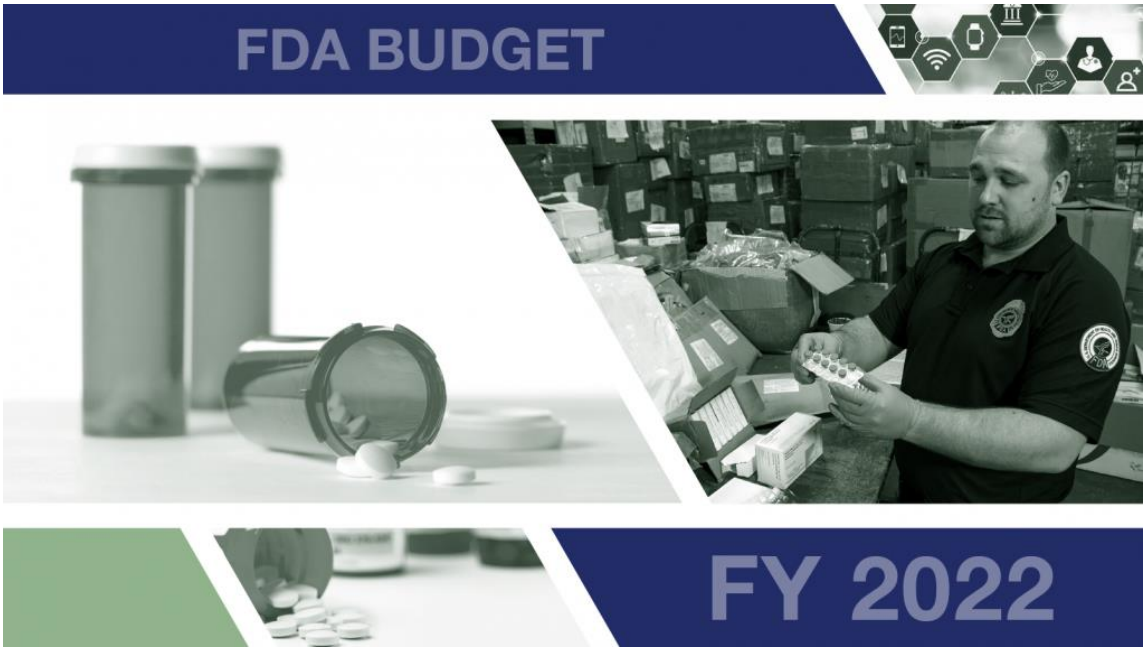
severe infestations, fleas feasting on your pet's blood can lead to anemia and, in rare cases, death.

Ticks can also harm your pet, transmitting tick-borne infections such as Lyme disease, Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, and Bartonellosis. And pets can bring ticks into the home, exposing you and your family to illness from a tick bite.

Read More

FDA Voices

FDA's Budget: Advancing the Goal of Ending the Opioid Crisis



By: Janet Woodcock, M.D., Acting Commissioner of Food and Drugs

As we confronted the COVID-19 pandemic over the past year, many of the existing public health challenges we face as a nation did not suddenly disappear. The opioid crisis in particular has remained an urgent public health priority for the U.S. Food and Drug Administration, particularly as the crisis has continued to expand, devastating families and communities across the nation.

The investments outlined in the FDA's FY 2022 budget request would address current public health needs and allow the agency to design programs intended to tackle complex challenges facing the country, such as those needed in addressing the opioid crisis, by supporting development of new therapies and smarter enforcement.

Read More

Webinars and Virtual Workshops

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments
The Food and Drug Administration (FDA or the Agency) is announcing an annual public meeting and opportunity for public comment on "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments." This public meeting is intended to meet performance commitments included in PDUFA VI, BsUFA II, and GDUFA II. These user fee programs were reauthorized as part of the Food and Drug Administration Reauthorization Act of 2017 (FDARA) signed by the President on August 18, 2017.

June 28, 2021; 2:00 PM - 4:00 PM ET

Registration is not required.

SARS-CoV-2: Host-pathogen interaction, vaccines & variants of concern
Professors Carroll and Hiscox's studies reveal how the human body responds to severe SARS-CoV-2 infection which will help in future treatments of COVID-19 patients. They will also present results on the immunological response to infection and vaccination, in addition to the potential impact of new variants of the virus that are continuously evolving.

July 8, 2021; 12:00 PM - 1:00 PM ET

Register Here

Regulatory Education for Industry (REdI) Annual Conference 2021
Featuring three medical product center tracks: Drugs, Devices, and Biologics

Learn directly from the FDA's regulatory experts in medical product centers: drugs, devices, and biologics. This course is designed to provide participants with a strong, basic foundation in the FDA's regulatory requirements. View Agenda.

July 19 - 23, 2021; 8:40 AM - 4:10 PM ET

Register Here

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics VI (GREAT VI) Workshop on Eosinophilic Gastrointestinal Disorders Beyond EoE
The goal of the GREAT VI workshop is to discuss disease characteristics, natural

history, and endpoints to assess treatment benefit in patients with eosinophilic gastrointestinal disorders beyond eosinophilic esophagitis and provide a forum for open discussion between stakeholders to facilitate drug development in these disorders.
July 21, 2021; 10:00 AM - 3:30 PM ET

Register Here

FDA PUBLIC WORKSHOP: 6th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop
The overarching aim of this year's workshop remains the same as in past years - to provide a forum for collaborative and productive multidisciplinary discussions to advance the understanding of the complex regulatory, health care policy, and scientific issues surrounding the use of patient-reported outcome (PRO) measures in cancer clinical trials. The workshop will be open to the public, fully virtual, and divided into two half-days. During the four sessions of this workshop, we will focus our discussion on regulatory-grade patient-generated data on physical function (defined as the ability to carry out day-to-day activities that require physical effort) in cancer clinical trials.

July 21 - 23, 2021

Day 1: Wednesday, July 21, 2021; 1:00 PM - 4:00 PM ET

Day 2: Friday, July 23, 2021; 9:00 AM - 12:00 PM ET

Register Here

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics VI (GREAT VI) Workshop on Celiac Disease
The goal of the GREAT VI workshop is to discuss the overall approach to drug development in celiac disease that includes an assessment of both clinical symptoms and histology. The workshop will focus the discussion on the histologic endpoints to assess treatment benefit in patients with celiac disease; regulatory framework for pediatric drug development in celiac disease; and the role of gluten challenge in clinical trials to provide a forum for open discussion between stakeholders to facilitate drug development.

July 22, 2021; 9:00 AM - 3:30 PM ET

Register Here

About Us

The FDA Stakeholder Engagement Staff reside within the Office of the Commissioner and support the FDA mission by engaging with Patient and Health Professional Organizations, Consumer Groups, Trade Associations, Think Tanks and other external stakeholders. We encourage and support active engagement from external stakeholders related to policy that impacts human and animal medical products, cosmetics, tobacco, nutrition and food safety that promote health and healthy living.