
# Center for Drug Evaluation and Research

## *What's New in Regulatory Science*

Spring 2021

**Brought to you by the Office of Translational Sciences (OTS) in collaboration with the Office of Communications within the Center for Drug Evaluation and Research (CDER)**

*What's New in Regulatory Science* is a quarterly newsletter from the Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER). It features new developments, opportunities, and initiatives in drug development regulatory science, with the goal of advancing medical product development.

Please share this message and the sign-up link with colleagues. If you have comments or questions, please contact us at OTSCommunications@fda.hhs.gov.

**COVID-19 - FDA NEWS RELEASES AND ALERTS**

- FDA issues an Emergency Use Authorization (EUA) for monoclonal antibodies, bamlanivimab and etesevimab, administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]), who test positive for SARS-CoV-2 and are at high risk for progressing to severe COVID-19.

- FDA Revokes Emergency Use Authorization for Monoclonal Antibody Bamlanivimab that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients.

- FDA alerts health care professionals and compounders of potential risks associated with the compounding of remdesivir drug products.

- FDA issues an Emergency Use Authorization (EUA) for Propofol-Lipuro 1% injectable emulsion for infusion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an intensive care unit setting during the COVID-19 public health emergency.

- FDA launches a new COVID-19 EUA FDA Adverse Events Reporting System (FAERS) Public Dashboard

# COVID-19 UPDATES

The FDA is engaged in numerous activities to protect and promote public health during the COVID-19 pandemic. For CDER, these efforts include accelerating development of treatments for COVID-19, maintaining and securing drug supply chains, providing guidance to stakeholders, advising developers on how to handle clinical trial issues, and keeping the public informed. Information on some of CDER's efforts related specifically to drugs and COVID-19 can be found here in the 2020 issues of the newsletter. Recent updates are provided below:

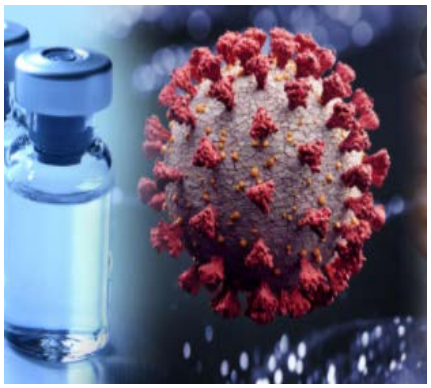
- Coronavirus (COVID-19) Drugs Web Page
- FDA COVID-19 Response At-A-Glance Summary as of March 26, 2021
- FDA's Generic Drug Program in 2020 Helped Ensure Availability of High-Quality, Affordable Drugs Amid COVID-19.
- FDA issued a new guidance: Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency.
- FDA has revised a second guidance covering drugs and biological products more broadly for COVID-19: COVID 19: Developing Drugs and Biological Products for Treatment or Prevention.
- FDA issued a guidance to help protect consumers from methanol poisoning: Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).

- The FDA and the NIH CURE ID app has received the 2021 Golan Christie Taglia Patient Impact Philanthropy Award from Cures Within Reach. CURE ID is an internet-based repository that lets the clinical community share novel uses of existing drugs for difficult-to-treat infectious diseases. The FDA and the NIH have made critical updates to CURE ID to be a more effective tool during COVID-19.

- FDA updates on hand sanitizers consumers should not use

- COVID-19 Educational Material and Other Resources

## SPOTLIGHT ON CDER SCIENCE



**FDA's approval of Veklury (remdesivir) for the treatment of COVID-19—The Evidence for Safety and Effectiveness in November of 2020.**

Veklury became the first drug approved by FDA as a treatment for COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization in October 2020. The scientific evidence from the Adaptive COVID-19 Treatment Trial (ACTT-1) trial, combined with FDA's assessment of the SIMPLE trials, supported the determination that the standard for substantial evidence of effectiveness and demonstration of safety as required for a new drug approval were met and that the benefit of treatment with Veklury included a shorter time to recovery and better odds of clinical improvement. Learn more.

## REGULATORY SCIENCE IMPACT STORIES

CDER is continuing to highlight its regulatory science research in a series of regulatory science impact stories. Recent posts include:

**Using Artificial Neural Networks to Predict Drug Response**

Pharmacokinetic (PK) models of drug exposure and pharmacodynamic (PD) models of drug response help us predict how drugs will affect the highly diverse patients that need them. Applying concepts from deep learning, CDER researchers constructed a type of artificial neural network that is especially suited to sequential pharmacologic data. When trained on simulated data from a traditional PK/PD model for a set of patients on once-daily drug regimens, this neural network learned to predict PD response even when the drug dosing regimen was changed. The researchers comment on how complimentary use of deep learning and traditional modeling approaches may help us to better predict drug responses in patients. Learn more.

**How computational analysis of a 3D mucociliary clearance model can help predict drug uptake and lead to more generic nasal drug products**

In 2020, CDER's Office of Generic Drugs (OGD) and several partner researchers quantified the effect of drug solubility and partition coefficient on the dissolution and subsequent uptake of drugs in a realistic nasal cavity model. Complex locally acting generic drug products, such as some orally inhaled or nasal drug products, can be more challenging for generic drug developers to copy, often leading to a lack of generic competition even after patents and exclusivities no longer block generic drug approval. Accurate and realistic predictions from computer simulations about deposition and absorption of nasally inhaled drugs can provide a deeper understanding of complex fluid-particle dynamics in the nasal cavity which may help OGD clarify regulatory expectations early in the drug development process and during application assessment. Learn more.

# IN PRESS

**Recent Scientific Publications by FDA/CDER Staff can be found** here
Some examples are provided below:

**Conveying risk in direct-to-consumer drug ads**

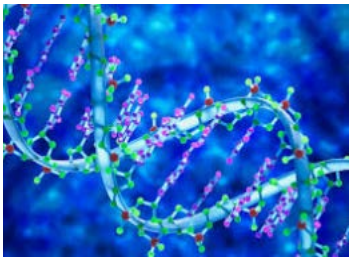
CDER's pilot study suggests that "framing statements" containing information on the severity of possible adverse effects may help consumers make more informed decisions about the product's risks. Learn more.

**FDA modernizes the review of NDAs**

The testing, implementation, and rationale of the new Integrated Assessment process and Integrated Review document are explained by CDER reviewers. Learn more.

**Reducing impurities during solid phase synthesis of nucleic acid-based drugs**

As therapeutics consisting of DNA or RNA show increasing promise, CDER researchers have found a way to decrease potentially harmful impurities generated during the synthesis of these molecules. Learn more.

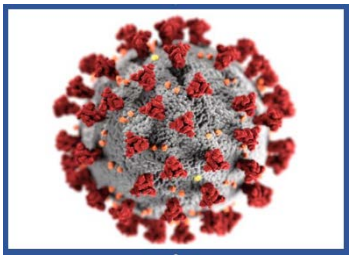


**A Bayesian approach in pediatric cancer clinical trials**

CDER statisticians show how innovative Bayesian approaches can be used to design, monitor, and analyze pediatric trials. Learn more.

**Screening FDA-approved drugs against multiple targets of SARS-CoV-2**

CDER researchers working with external collaborators present a novel strategy for in-silico molecular modeling screening for potential drugs that may interact with proteins of SARS-CoV-2. Learn more.



# UPCOMING EVENTS

Information on upcoming meetings, conferences, and workshops sponsored or co-sponsored by CDER, click here.

Some of the events are listed below:

1. April 14-16, 2021: The 15th Annual FDA/DIA Biostatistics Industry and Regulator Forum 2021
2. April 20-22, 2021: FDA/CDER and AASLD 2021 DILI Conference XVIII
3. April 27-29, 2021: Meeting of the Oncologic Drugs Advisory Committee Meeting Announcement

June 23, 2021: FY 2021 Generic Drug Science and Research Initiatives Public Workshop


FDA continues to recruit and retain a world-class workforce dedicated to protecting and promoting public health. Information on job vacancies, employment events, and hiring programs can be found by following @FDAJobs on Twitter and by visiting FDA's LinkedIn page, Jobs at CDER, or the Career Opportunities at CDER webpage. In addition, you can contact OTS directly at CDEROTSHires@fda.hhs.gov. Help us spread the news through your social media networks!

For more information, please visit the FDA In Brief Webpage.

Scientific Internships and Fellowships / Trainees and Non-U.S. Citizens

# CAREER OPPORTUNITIES

Whether you're an undergraduate looking to pursue a career in science, a graduate student seeking experience in regulatory science, a postgraduate looking for fellowship opportunities, or a senior scientist pursuing research experience in your field of expertise, FDA offers you many paths to learning about the exciting field of regulatory science. Click here for more information.