



CENTER FOR DRUG EVALUATION AND RESEARCH
What's New in Regulatory Science



Fall/Winter Issue 2021

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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 (Select Regulatory Science as the Topic Area). If you have comments or questions, please contact us at OTSCcommunications@fda.hhs.gov.

COVID-19- RELATED EFFORTS

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 in the 2020 and the 2021 issues of the newsletter (click [here](#) to access the 2020 and 2021 issues) and at the webpages below:

- [Coronavirus \(COVID-19\) Drugs Web Page](#)
- [Center for Drug Evaluation and Research \(CDER\) Response to Coronavirus \(COVID-19\) Infographic](#) as of September 30, 2021
- [FDA updates on hand sanitizers consumers should not use](#)
- [COVID-19 Educational Material and Other Resources](#)

Some recent updates are provided below:

COVID-19 EMERGENCY USE AUTHORIZATIONS AND UPDATES

- ***FDA makes changes to the authorized use of the monoclonal antibodies bamlanivimab and etesevimab, administered together.***

August 27, 2021: The Emergency Use Authorization(EUA) now authorizes the use of bamlanivimab and etesevimab, administered together, only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%. Read more [here](#).

September 2, 2021 Update: Based on FDA's evaluation of the most recently available SARS-CoV-2 variant frequency data, bamlanivimab and etesevimab, administered together, can be used in all U.S. states, territories, and jurisdictions under the conditions of authorization for EUA 94. Read more [here](#).

September 16, 2021: The FDA revised the EUA for bamlanivimab and etesevimab, administered together, to include an emergency use as post-exposure prophylaxis (prevention) for COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) who are at high risk for progression to severe COVID-19, including hospitalization or death. Read more [here](#).

- ***FDA approves an abbreviated new drug application on September 3, 2021 for dexmedetomidine injection USP, 200 mcg/2 mL***, indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting and sedation of non-intubated patients prior to and/or during surgical and other procedures. Read more [here](#).



Why you should not use ivermectin to treat or prevent COVID-19

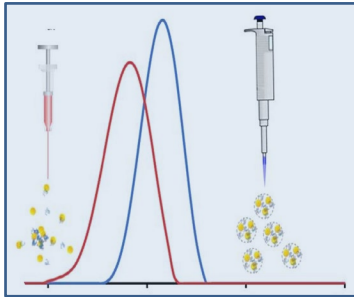
Some people are taking the drug ivermectin, in some cases the version intended for animals, to try to prevent or treat COVID-19. FDA has not approved or authorized ivermectin for this use and it may be unsafe to use the drug for this purpose. Read more [here](#).

FDA Issues COVID-19 Relevant Guidances

- ✓ September 9, 2021: The FDA revised the guidance, “[Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers](#)”, originally published in April 2021.

REGULATORY SCIENCE IMPACT STORIES

Improving dosing for injectable suspensions



The sustained release characteristics of most FDA-approved injectable suspensions make them both convenient and clinically beneficial. However, their prolonged release and the higher drug amount in one dose may pose risks to patients. Recent CDER research improves our understanding on how the method of administration may help explain the pharmacokinetic variability in these products while providing insights as to how their dosing can be improved. [Learn more.](#)

Improving prescribing of renally cleared drugs in children



To determine the proper dose of renally cleared drugs in children, various “estimated glomerular filtration rate (eGFR) equations” are widely used to approximate renal function, which changes rapidly as children develop. Using pharmacokinetic data from pediatric trials as a reference, CDER researchers found that these equations were likely to overestimate clearance, in part due to difficulties in measuring low serum creatine levels. [Learn more.](#)

Safer regimens for antibiotics



A CDER-supported project at Johns Hopkins University used a novel automated method for extracting data from electronic health records to determine the safest and most effective treatment durations for two kinds of bacterial infections. The results provide valuable evidence to inform best practices related to the duration of antibiotic treatment in diverse bacterial infections, optimizing patient outcomes while reducing the risk for antimicrobial resistance. [Learn more.](#)

IN PRESS

This section provides highlights from select CDER research publications. [Click here](#) to see the complete FDA publication list. Look up the Drugs section for CDER Publications.



An innovative PBPK-based absorption modeling approach to support generic drug development

CDER researchers propose coupling of physiologically-based pharmacokinetic modeling with Bayesian population modeling approaches towards establishing dissolution specifications within the context of a virtual bioequivalence assessment for bupropion hydrochloride oral dosage forms.

[Learn more.](#)

Racial and ethnic differences in drug disposition and response

CDER researchers evaluated recently approved NMEs, including whether interracial or interethnic differences in pharmacokinetics, safety, or efficacy were reported in the labeling and the extent of ethnic subgroup participation in the pivotal and supportive trials supporting drug approvals. Learn more. [Learn more.](#)

Risks of severe outcomes in elderly COVID-19 patients taking anti-hypertensive drugs

CDER and CBER researchers report on their observational case-control study to determine if treatment of elderly patients with ACEIs and ARBS is associated with increased risk of hospitalization and other adverse outcomes.

[Learn more.](#)

Assessing the standard of care for hormone receptor-positive, HER2-advanced breast cancer

CDER researchers provide results of overall survival in a pooled, patient-level analysis of FDA-approved cyclin-dependent kinase 4/6 inhibitors in combination with fulvestrant. [Learn more.](#)

Applications and outcomes under the Competitive Generic Therapy (CGT) program

CDER reviewer-researchers analyzed the characteristics and outcomes of generic drug products that have sought CGT designation and those that were granted CGT exclusivity. [Learn more.](#)

UPCOMING EVENTS

Information on upcoming meetings, conferences, and workshops sponsored or co-sponsored by CDER, click [here](#).

One of the events is listed below:

1. December 7 and 8, 2021: "[Clinical Investigator Training Course \(CITC\) Update](#)"
2. January 24 and 25, 2022: : "[Endpoint Considerations to Facilitate Drug Development for Niemann-Pick Type C \(NPC\) Public Workshop](#)"

CAREER OPPORTUNITIES



You want to make a
difference.

FDA wants to hire
You.

Employment

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!

Scientific internships and fellowships

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.

Translational Science Interagency Fellowship (TSIF): The Translational Science Interagency Fellowship (TSIF) program is jointly sponsored by NCATS and the U.S. Food and Drug Administration (FDA) and aims to provide training in both translational science and regulatory science. Submit your applications by **January 17, 2022**. [Learn more](#).