



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

FDA

Issue I - 2022

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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](#)
- [FDA updates on hand sanitizers consumers should not use](#)
- [COVID-19 Educational Material and Other Resources](#)

Some recent updates are provided below:

COVID-19 APPROVALS. EMERGENCY USE AUTHORIZATIONS AND UPDATES

- ***FDA Approves First COVID-19 Treatment for Young Children***

April 25, 2022: The FDA expanded the approval of the COVID-19 treatment Veklury (remdesivir) for pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral testing, who are: Hospitalized, or Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. Read more [here](#).

- ***FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals***

December 3, 2021: The FDA issued an emergency use authorization (EUA) for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms [about 88 pounds]). Read more [here](#).

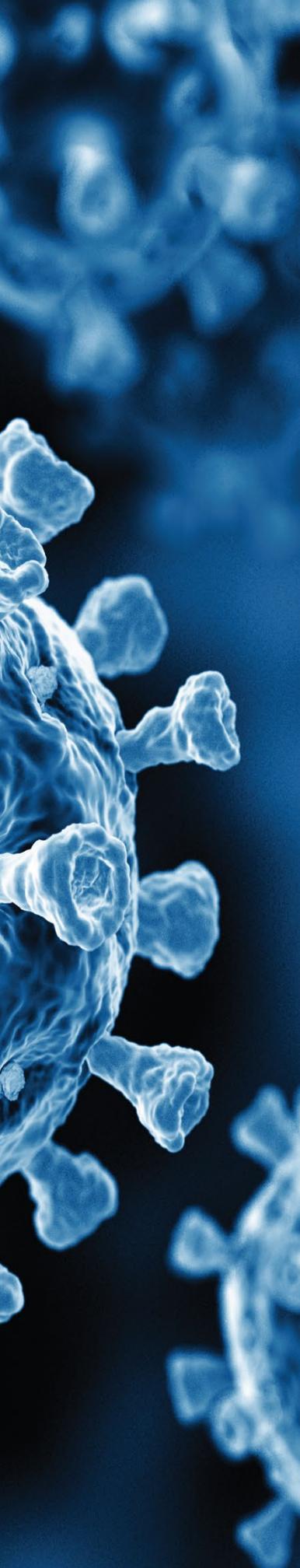
- ***FDA Authorizes First Oral Antiviral for Treatment of COVID-19***

December 22, 2021: The FDA issued an emergency use authorization (EUA) for Pfizer's Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Read more [here](#).

- ***FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults***

December 23, 2021: The FDA issued an emergency use authorization (EUA) for Merck's molnupiravir for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. Read more [here](#).

- ***FDA Authorizes New Monoclonal Antibody, Bectelovimab, for Treatment of COVID-19 That Retains Activity Against Omicron Variant***



February 11, 2022: The EUA for bebtelovimab is for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms, which is about 88 pounds) with positive results of direct SARS-Cov-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. Read more [here](#).

FDA Expands Authorization of Two Monoclonal Antibodies for Treatment and Post-Exposure Prevention of COVID-19 to Younger Pediatric Patients, Including Newborns

December 3, 2021: The FDA revised the emergency use authorization (EUA) of bamlanivimab and etesevimab administered together (previously authorized for pediatric patients 12 years of age and older weighing at least 40 kilograms, or about 88 pounds), to additionally authorize bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in all younger pediatric patients, including newborns, with positive results of direct SARS-Cov-2 viral testing and are at high risk for progression to severe COVID-19, including hospitalization or death. Read more [here](#).

- ***FDA Expands Use of Treatment for Outpatients with Mild-to-Moderate COVID-19***

January 21, 2022:

The FDA has expanded the approved indication for Veklury (remdesivir) to include its use in adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

The agency also revised the Emergency Use Authorization (EUA) for Veklury to additionally authorize the drug for treatment of pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death. Read more [here](#).

- ***FDA updates the Health Care Provider Fact Sheets for bamlanivimab and etesevimab administered together, REGEN-COV, and sotrovimab with specific information regarding expected activity against the Omicron variant (B.1.1.529/BA.1).***

December 23, 2021: The data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant. Based on similar cell culture data currently available, sotrovimab appears to retain activity against the Omicron variant. Read more [here](#).

- ***FDA updates Sotrovimab Emergency Use Authorization***

February 25, 2022: FDA revised the emergency use authorization for sotrovimab to clarify that sotrovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a variant that is not susceptible to this treatment. Read more [here](#).

April 5, 2022: Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant. Read more [here](#).

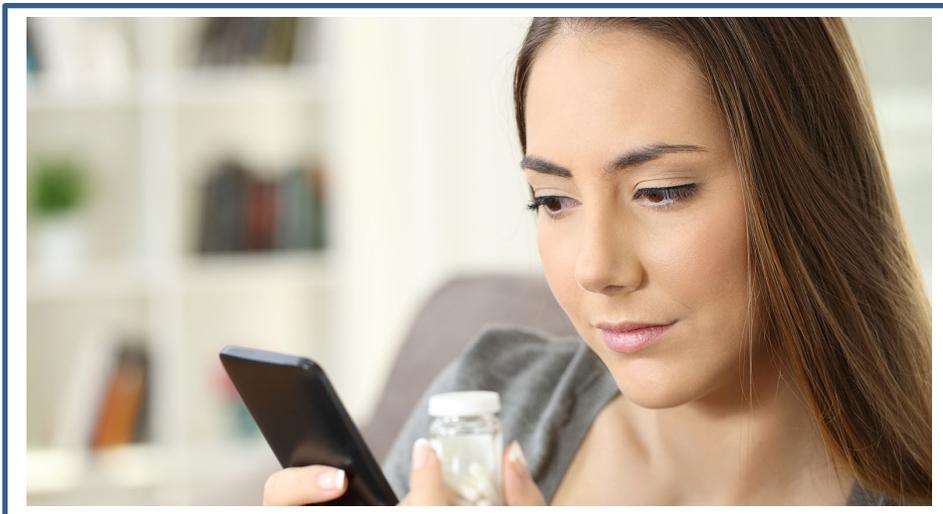
- ***FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant***

January 24, 2021: Based on the most recent information and data available, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments. Read more [here](#).

REGULATORY SCIENCE IN ACTION

SPOTLIGHT ON CDER SCIENCE

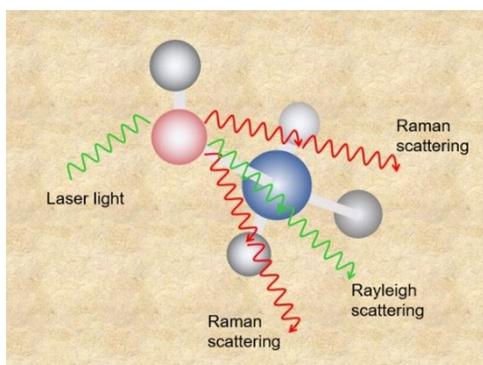
Learning from Patient Text Messaging to Optimize Opioid Prescribing and Reduce Misuse



The nonmedical use of opioids prescribed by a physician is the second most common type of illicit drug use in the US. An automated text messaging program developed by CDER-funded researchers and collaborators provides an efficient way for caregivers to understand patient needs for these drugs after surgery and ensure they have the medications they need for pain relief while preventing prescription of excess amounts drugs that may be subject to misuse or abuse. This new approach to gathering needed information from patients may be useful for developing improved prescribing guidelines in diverse clinical contexts. [Learn more.](#)

REGULATORY SCIENCE IMPACT STORIES

A novel method for rapid screening of hand sanitizers



Many imported hand sanitizers used during the COVID pandemic were found to be ineffective, or contaminated with methanol, which can lead to serious toxicity. To address this problem, CDER researchers made use of a recent innovation in Raman spectrometry to develop a non-invasive, “through-container” and quantitative screening method that can be carried out in just a few seconds. [Learn more.](#)

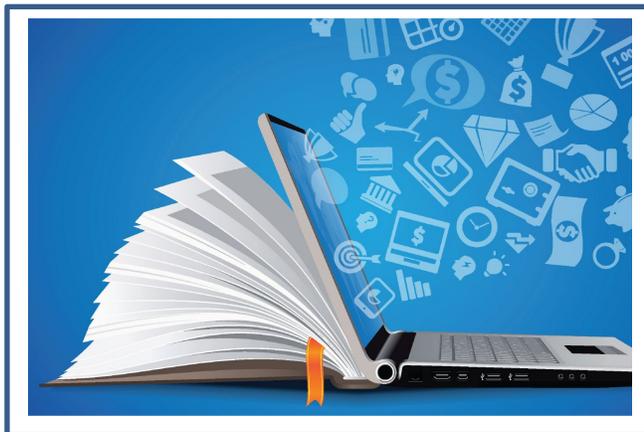
How modeling was used to support approval of a topical generic drug product



CDER researchers have been investigating how pharmacokinetic modeling can support a determination of bioequivalence for topical drug products. In the case of a generic version of diclofenac sodium topical gel, a nonsteroidal anti-inflammatory drug for relief of the pain of osteoarthritis of joints amenable to topical treatment, CDER scientists found that physiologically based pharmacokinetic modeling could support an alternative bioequivalence approach that did not include a comparative clinical endpoint study. [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.



A Bayesian population PBPK absorption modeling approach to support generic drug development

Through model building and simulations, CDER researchers demonstrate how PBPK modeling, enhanced by Bayesian methodology and *vitro* and *in vivo* information, can be used to inform decisions related to generic drug product development. [Learn more.](#)

Early antibody responses associated with survival in COVID19 patients

Using a highly sensitive multiplexed bead-based immunoassay, CDER investigators found that early appearance of anti-SARS-CoV-2 antibodies was associated with survival in patients hospitalized with COVID 19. [Learn more.](#)

Single in-line biomass probe detects CHO cell growth by capacitance and bacterial contamination by conductivity in bioreactor

CDER investigators have demonstrated the feasibility of using in line conductivity measurements for early detection of bacterial contamination in bioreactors used to grow cells that express protein biologics. [Learn more.](#)

Characterization of the therapeutic effect of antibodies targeting the Ebola glycoprotein using a novel BSL2-compliant rVSVΔG-EBOV-GP infection model

CDER researchers demonstrated that a mouse model suitable for biosafety level 2 laboratories can be used to screen therapeutics targeting the Ebola virus surface glycoprotein and to investigate their effects on viral clearance in different tissues. [Learn more.](#)

Retrospective analysis of clinical trial safety data for pembrolizumab reveals the effect of co-occurring infections on immune-related adverse events

Biologics targeting immune check-point proteins can cause adverse events, resulting in discontinued therapy or fatal outcomes. CDER researchers analyzed over 10,000 AE reports from trials of pembrolizumab and found a statistically significant increase in the risk of immune-related adverse events in patients with infections. [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 26 and 27, 2022: [FY 2022 Generic Drug Science and Research Initiatives Public Workshop](#)
2. May 9 and 10, 2022: : [Generic Drugs Forum 2022: The Current State of Generic Drugs](#)
3. May 16 and 17, 2022: [Pharmacokinetic Evaluation in Pregnancy-](#) (Virtual)
4. May 16 and 17, 2022: [FDA CDER & NIH NCATS Regulatory Fitness in Rare Disease Clinical Trials Workshop](#)
5. June 3, 2022: [Development Considerations of Antimicrobial Drugs for the Treatment of Uncomplicated Urinary Tract Infections \(UTI\)](#) (Virtual)
6. June 29, 2022: FDA-CRCG (Center for Research on Complex Generics) Workshop on In Vitro Release Test (IVRT) and In Vitro/In Vivo Correlation (IVIVC) of Complex Generic Ophthalmic, Injectable, Implantable, and Inserted Products. Learn [more](#).
7. October 27-28, 2022: FDA-CRCG Workshop on Using Model Integrated Bioequivalence (BE) Approaches in Complex Generic Product Development. Learn [more](#).
8. November 3, 2022: FDA-CRCG Workshop on Evaluation of Cutaneous Pharmacokinetics to Facilitate Complex Generic Topical Product Development. Learn [more](#).
9. December 6, 2022: FDA-CRCG Training on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Learn [more](#).

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.