



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



Issue II - 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 authorizes revisions to Evusheld (tixagevimab co-packaged with cilgavimab) dosing***
June 29, 2022: FDA authorizes revisions to Evusheld dosing to recommend repeat dosing every six months with a dose of 300 mg of tixagevimab and 300 mg cilgavimab if patients need ongoing protection. Read more [here](#).

June 28, 2022: The Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) announced the authorization of an extension to the shelf-life from 18 months to 24 months for specific lots of the refrigerated Evusheld under Emergency Use Authorization. Read more [here](#).
- ***FDA Authorizes Shelf-Life Extension for REGEN-COV (casirivimab and imdevimab) administered together) From 24 months to 30 Months***
June 27, 2022: FDA authorized an extension to the shelf-life from 24 months to 30 months for specific lots of the refrigerated Regeneron monoclonal antibodies, casirivimab and imdevimab, administered together (REGEN-COV). Read more [here](#).
- ***FDA provides additional guidance to help prescribers evaluate potential drug interactions when using Paxlovid therapy for COVID-19***
June 3, 2022: Prescribers should review each patient's full list of medications and use other resources to evaluate for potential drug interactions in patients who take medications that are not included on the Fact Sheet or checklist at this time. Please see the updated Prescriber Patient Eligibility Screening Checklist for more information. Read more [here](#).
- ***FDA and HHS/ASPR announce the authorization of an extension to the shelf-life of bebtelovimab***
May 20, 2022: The FDA and HHS/ASPR announced the authorization of an extension to the shelf-life from 12 months to 18 months for specific lots of the refrigerated Eli Lilly monoclonal antibody, bebtelovimab, which is currently authorized for emergency use. Read more [here](#).
- ***FDA approves a new indication for Olumiant (baricitinib) for the treatment of COVID-19***
May 10, 2022: The FDA approved a new indication for Olumiant (baricitinib) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Read more [here](#).

REGULATORY SCIENCE IN ACTION

REGULATORY SCIENCE IMPACT STORIES

Testing Metered Dose Inhalers



Metered dose inhalers (MDIs) are drug-device combination products that generate aerosols suitable for pulmonary drug delivery and are mainstays in the treatment of asthma, COPD, and other respiratory diseases. CDER researchers conducted a systematic analysis of the effects of five different experimental factors on the size distribution of aerosol particles and droplets emitted from these products. Based on their results, they offered recommendations for developers.

[Learn more.](#)

Extrapolating Drug Efficacy to Children



For many drugs that have been tested in adults, evidence as to their efficacy in children is lacking. Based on experience in pediatric drug development programs, CDER researchers developed a quantitative framework to assess exposure-response similarity in pediatric and adult patients. This framework for applying a non-inferiority paradigm eliminates subjective interpretation of the data and can provide quantitative evidence to help regulators make important decisions about the appropriate use of new drugs in children.

[Learn more.](#)

Trials Designs that Incorporate Real World Data



In certain clinical trial scenarios, such as in pediatric dose finding or when the treatment being evaluated is for a rare and rapidly progressing disease, it may be especially important to leverage real world data as evidence. CDER statisticians have been investigating how to incorporate real world evidence rigorously and transparently in clinical studies in situations where it would not be feasible or ethical to include a control arm. [Learn more.](#)

SPOTLIGHT ON CDER SCIENCE

Addressing Concerns About Generic Drugs to Treat Hypothyroidism



CDER-sponsored researchers reviewed a national claims database to assess the clinical management of thyroid function among patients undergoing treatment with approved levothyroxine products (either generic or brand-name). By robustly matching patient populations, they showed that patients who switched among different generic levothyroxine products maintained the same degree of thyroid health as patients who consistently used a single product. Despite medical guidelines that have urged prescribers to avoid switching between levothyroxine products, this recent CDER analysis confirms that prescribers can regard FDA-approved generic drugs for this indication—even those with a narrow therapeutic window—as interchangeable. [Learn more.](#)

IN PRESS

This section provides highlights of select CDER research recently published in scientific journals. [Click here](#) to see the complete FDA publication list. Look up the Drugs section for CDER Publications.



A Critical Overview of The Biological Effects of Excipients

CDER researchers critically review the biological effects of excipients, including how an excipient can influence in vivo gastrointestinal physiology ([Part 1](#)) and how in vitro, in vivo, and in silico methods have been used to promote formulation understanding and optimization ([Part II](#)).

Systemic Corticosteroid Use for COVID-19 in the US

CDER's analysis of data from Medicare and FDA's Sentinel System found that large numbers of non-hospitalized virus patients nationally were being prescribed systemic corticosteroids despite National Institutes of Health (NIH) guidance to the contrary. [Learn more.](#)

Modeling the evolution of the US opioid crisis for national policy development

CDER researchers present an operationally detailed, national-level model of the opioid crisis intended to enhance understanding of the crisis and guide policy decisions. [Learn more.](#)

Quantitative methods and modeling to assess COVID-19- interrupted in vivo BE studies

CDER researchers used quantitative methods and modeling to evaluate the impact of using two batches of a reference product to evaluate bioequivalence of a generic when this is required due to reference product expiration. The study was intended to provide insight to developers in situations where BE studies are interrupted. [Learn more.](#)

Landscape Analysis of the Application of AI and Machine Learning in Regulatory Submissions

From 2016 to 2021, CDER researchers found an increasing number of drugs in which AI and machine learning were applied to a variety of tasks, including drug discovery and repurposing, clinical trial design, dose optimization, endpoint- and biomarker assessment, and postmarketing surveillance. [Learn more.](#)

Phase Behavior and Crystallization of a Poorly Soluble Drug as a Function of Supersaturation and Media Composition

To help predict oral drug absorption, CDER researchers sought to understand the supersaturation and precipitation behavior of poorly water-soluble compounds. [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. October 27-28, 2022: FDA-CRCG Workshop on Using Model Integrated Bioequivalence (BE) Approaches in Complex Generic Product Development. Learn [more](#).
2. November 3, 2022: FDA-CRCG Workshop on Evaluation of Cutaneous Pharmacokinetics to Facilitate Complex Generic Topical Product Development. Learn [more](#).
3. November 9, 2022: Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches. Learn [more](#).
4. 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.

FDA-NCATS 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. The application cycle starts on September 19, 2022. Submit your applications by **January 20, 2023**. [Learn more.](#)