



U.S. FOOD & DRUG
ADMINISTRATION

State of CDER

FDLI Annual Conference

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CDER's 3 key priorities during the COVID public health emergency include:

1. Working with drug companies and investigators to bring safe and effective drugs for COVID-19 to the public as soon as possible
2. Monitoring the nation's supply of medicines and taking action to mitigate or prevent drug shortages
3. Working to help ensure the health of *all* patients

Consistent stakeholder engagement and collaboration are foundational to these priorities

CDER is facing a number of challenges, but we are also trying to address them via innovative approaches.

We know industry is facing challenges such as:

- **Conducting clinical trials**
 - **Reduced ability to conduct on-site inspections**
 - **Meeting regulatory requirements**
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- **We're able to reduce impact by providing guidance to help our stakeholders navigate this uncharted territory**

CTAP Treatment Acceleration Program

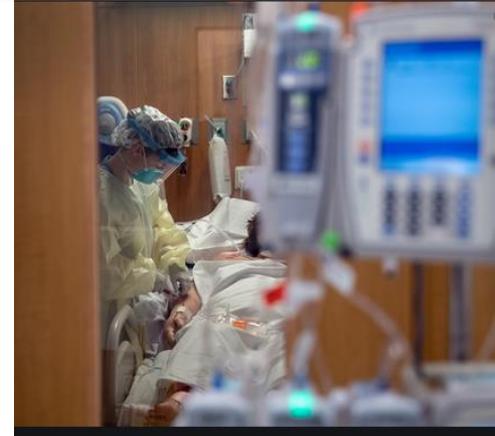


Coronavirus Treatment Acceleration Program (CTAP)

CTAP will use every available method to move new treatments to patients as quickly as possible, balancing patient needs for medicine while supporting trials to gather evidence and weighing the risks and benefits

As of August 31:

- Over 590 drug development programs in planning stages*
- Over 310 trials reviewed by FDA**
- 5 treatments authorized for Emergency Use



*Active Pre-INDs excluding vaccines

**Safe to proceed IND excluding vaccines

CDER has been monitoring the drug supply chain to prevent or mitigate drug shortages

- Expediting new guidance to bolster drug supply (including manufacturing and inspections¹)**
- Proactively working with manufacturers to evaluate supply chains and exercise regulatory flexibility and discretion when appropriate, without compromising safety**
- Outreach to hospitals, pharmacists, and clinicians**
- Leveraging real-world data to understand drug usage and demand**

¹ [Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers](#)

Appropriate regulatory flexibility and discretion to meet critical needs

- **Guidance on compounding by outsourcing facilities and pharmacies not registered as outsourcing facilities for certain drugs used for hospitalized patients with COVID-19**
- **Emergency Use Authorization to address shortages – propofol, dialysate fluid**
- **Expedited review and approval of generic drugs**
- **Assisting new and established manufacturers to produce alcohol-based hand sanitizer and ethanol for use in hand sanitizers during the COVID-19 pandemic**
 - **Since March 1, 2020, more than 3,500 new hand sanitizers manufacturers have registered with FDA**

Regulatory Action to Protect Public Health

FDA has taken action against sellers of fraudulent products for the treatment or prevention of COVID-19, including issuing more than 90 warning letters. FDA has also warned consumers of contaminated and subpotent hand sanitizer that the Agency advises consumers not use.

FDA NEWS RELEASE

COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

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For Immediate Release: August 27, 2020

8/24/2020: UPDATE - FDA provides testing method to assess the quality of hand sanitizer products for impurities 

8/12/2020: UPDATE - FDA expands hand sanitizer warnings to include 1-propanol contamination 

8/7/2020: UPDATE - FDA Includes Methanol Testing in Temporary Policies for Alcohol-Based Hand Sanitizers 

7/31/2020: UPDATE - FDA continues to find issues with certain hand sanitizer products 

7/27/2020 PRESS RELEASE - Coronavirus (COVID-19) Update: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products 

7/2/2020: UPDATE - FDA warns consumers of risk of methanol contamination in certain hand sanitizers 

Maintaining Focus on Other Critical CDER Activities



- **Continuous work to support development of safe, effective, high quality therapies for rare diseases, cancer, diabetes, heart disease, autoimmune conditions, neurological conditions, substance use disorders, and many other diseases and conditions**
- **Ongoing assessment, surveillance, compliance, and pharmaceutical quality efforts across all regulated products**
- **Helping to ensure access to affordable, life-saving drugs and other needed medications**
- **UFA Reauthorization**
- **Implementing FDA's new OTC monograph reform authorities**
- **Establishment of Compounding Quality Center of Excellence**
- **Continued collaboration with industry to encourage and facilitate the adoption of Advanced Manufacturing**

Novel Drug Approvals

Since January 1, FDA has approved more than 40 novel drugs and therapeutic biological products (i.e., those never before approved or marketed in the U.S.), including many innovative therapies to treat a variety of cancers and other conditions

Generic Drug Approvals

Since January 1, FDA has approved more than 488 generic drug applications, including at least 42 first generics, such as the first generic of a widely used inhaler to treat patients with breathing conditions

It's Important for CDER to Stay Connected

- From January 1 to September 30, CDER fielded more than 49,909 inquiries from the general public, including health care providers, consumers and manufacturers, regarding medications; this total included more than 15,600 inquiries specifically related to COVID-19
- CDER will continue our work to advance treatments related to COVID-19, while also staying focused on other critical areas that are non-COVID-19 related
- We will maintain communications with stakeholders to keep you updated on recent items of possible interest, such as regulatory actions, guidances, and webinars
- Please reach out to us with questions at druginfo@fda.hhs.gov or (855) 543-3784

QUESTIONS?