

Center for Drug Evaluation and Research Response to COVID-19

FDA

Timeline: January 1, 2020 – September 30, 2021



COVID-19 Therapeutic Development:



- 640+ drug development programs in planning stages



- 470+ trials reviewed by FDA



- 11 treatments currently authorized for emergency use
- 1 treatment currently approved by FDA

Regulatory Flexibility: Proactively issued temporary policies to address the pandemic and provide regulatory flexibility on:



- Certain drugs compounded for hospitalized patients with COVID-19



- Repackaging or combining Propofol



- Prescription Drug Marketing Act requirements for distributing prescription drug samples
- Drug Supply Chain Security Act requirements



Generic Drug Approvals (Abbreviated New Drug Applications):

Approved **1,000+** original and supplemental generic applications for COVID-19 related treatments and supportive therapies



Addressing Fraud:

Took action against sellers of **fraudulent products** for the treatment or prevention of COVID-19, and issued more than **120 warning letters**



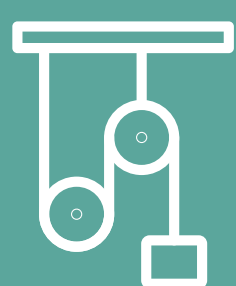
Internet Pharmacies:

Issued **17 warning letters** to operators of websites that sell unapproved and misbranded COVID-19 products



Hand Sanitizer:

Published a list with more than **250 listings** of hand sanitizers consumers should not use, including those containing potentially dangerous contaminants



Shortage Mitigation Activities:

Continued outreach to more than **180 manufacturers** relating to manufacturing capacity and supply chain for both COVID-19 and non-COVID-19 treatments



Surveillance and Epidemiology:

Examined and analyzed data across at least **15 data sources**, including **55,000 adverse event reports** to monitor drug safety and medication errors



U.S. Public Health Service

Corps Deployment:

Approximately **364 CDER Commissioned Corps officers** fulfilled **623 deployment requests** in support of the COVID-19 mission



Engagement With Stakeholders:

CDER fielded **23,515 COVID-19 drug related inquiries** from the general public, including health care providers, consumers and manufacturers

For more information, please visit <https://www.fda.gov/drugs>