






Center for Drug Evaluation and Research Response to COVID-19

FDA





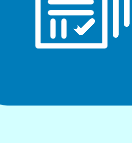
Timeline: January 1, 2020 – February 1, 2021



COVID-19 Therapeutic Development:

-  • 600+ drug development programs in planning stages
-  • 420+ trials reviewed by FDA
-  • 8 treatments currently authorized for emergency use
-  • 1 treatment currently approved by FDA
-  • More than 22 guidance documents for industry related to therapeutic development

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

-  • Certain drugs compounded for hospitalized patients with COVID-19
-  • Compounding and manufacturing of alcohol-based hand sanitizer
-  • Repackaging or combining Propofol
-  • Prescription Drug Marketing Act requirements for distributing prescription drug samples
-  • Drug Supply Chain Security Act requirements



Addressing fraud:

Took action against sellers of **fraudulent products** for the treatment or prevention of COVID-19, and issued more than **100 warning letters**



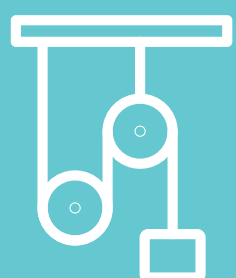
Internet pharmacies:

Issued **14 warning letters** to operators of websites that sell unapproved and misbranded COVID-19 products



Hand sanitizer:

Published a list with more than **200 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



U.S. Public Health Service Corps deployment:

Approximately **302 CDER Commissioned Corps officers** fulfilled **406 deployment requests** in support of the COVID-19 mission



Engagement with stakeholders:

CDER fielded **18,798 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>