Center for Drug Evaluation and Research Response to COVID-19

Timeline: January 1, 2020 – September 30, 2021

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

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

Generic Drug Approvals (Abbreviated New Drug Applications):
Approved 1,000+ original and supplemental generic applications for COVID-19 related treatments and supportive therapies

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

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

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

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

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

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

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