FDA COVID-19 RESPONSE

From the beginning of the COVID-19 public health emergency through the end of FY 2021 (September 30, 2021), FDA activities include:

REGULATORY ADVICE & GUIDANCE

- Issued 75+ COVID-19-related guidance documents
- Published 10 diagnostic test and 3 other medical device EUA templates
- Reviewed 470+ trials for COVID-19 therapeutics
- Worked with sponsors on 640+ drug development programs in planning stages

COVID-19 MCM APPROVALS*

*FDA-approved, licensed, or cleared

- 1 vaccine
- 1 treatment
- 1,000+ generic drug approvals for COVID-19 related treatments and supportive therapies
- 1 diagnostic test
- 492 personal protective equipment (PPE)
- 77 other devices

ADDRESSING FRAUD

- 1,500+ fraudulent and unproven products related to COVID-19 identified
- 260 warning letters sent to sellers
- 393 fraudulent test kits reported
- 320 online marketplace abuse complaints addressed
- 312 domain registrar abuse complaints addressed

EUAs

470+ EUAs issued enabling access to 750+ products

- 3 vaccines
- 13 drug and biological therapeutic products
- 390+ diagnostic tests and sample collection devices
- 18 PPE
- 44 other devices

COMMUNICATIONS

- 370+ COVID-19 update press releases
- 450+ new FDA web pages
- 11 Consumer Updates
- 15+ videos for consumers
- 16+ podcast episodes
- Thousands of tweets

STAKEHOLDER ENGAGEMENT

- 80+ MCMi email updates + hundreds more stakeholder emails
- 80 town halls on testing and PPE
- Answering public questions
  - 23,515 on COVID-19 drugs
  - 410,000+ on COVID-19 devices, including testing
  - 11,168 on COVID-19 vaccines
- Engaged with 2,200+ manufacturers on manufacturing capacity and supply chain issues