Center for Devices and Radiological Health’s Response to COVID-19

TIMELINE: JANUARY 1 — DECEMBER 28, 2020

REGULATORY FLEXIBILITY

Proactively issued policies to provide regulatory flexibility to address the pandemic

- 11 EUA TEMPLATES
- 26 GUIDANCE DOCUMENTS
- Including policies intended to help:
  - Car manufacturers making ventilators
  - Apparel manufacturers making masks
  - 3D printers making ventilator components

EMERGENCY USE AUTHORIZATIONS

608 MEDICAL DEVICES AUTHORIZED UNDER EUAs (ALMOST 10X THE NUMBER AUTHORIZED IN ALL PRIOR NATIONAL EMERGENCIES)

- 309 TESTS
  - 235 MOLECULAR
  - 11 ANTIGEN
- 63 ANTIBODY TESTS RECEIVED
- 1,995 Pre-EUAs
- 3,521 EUAs

SHORTAGE MITIGATION ACTIVITIES

Outreach to 1,000+ manufacturing sites across 12 countries to assess supply chain vulnerabilities

RESULT

Identified potential supply chain issues early and worked to minimize disruptions

PUBLIC HEALTH SERVICE CORPS DEPLOYMENT

61 CDRH Commissioned Corps officers have been deployed in support of the COVID-19 mission

ENGAGEMENT WITH STAKEHOLDERS

Sent 19M E-MAILS to stakeholders on COVID-19 topics

RESPONDED TO:

- 357,000 E-MAIL & PHONE QUERIES from patients, health care personnel, industry, & others
- 53 COVID-RELATED WEBINARS & TOWNHALLS WITH 44,000+ PARTICIPANTS

For more information, please visit fda.gov/medical-devices