

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

TIMELINE: JANUARY 1 — SEPTEMBER 18, 2020



REGULATORY FLEXIBILITY



Proactively issued policies to provide regulatory flexibility

to address the pandemic

10
EUA
TEMPLATES

&

23
GUIDANCE
DOCUMENTS

Including policies intended to help:

Car manufacturers making ventilators

Apparel manufacturers making masks

3D printers making ventilator components

EMERGENCY USE AUTHORIZATIONS



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

INCLUDING:

248
TESTS

OF WHICH ARE

198
MOLECULAR

4
ANTIGEN

46
ANTIBODY

TESTS

RECEIVED

1,734
Pre-EUAs

3,040
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



58
CDRH
Commissioned
Corps officers

HAVE BEEN
DEPLOYED

78
TIMES

in support of the COVID-19 mission

ENGAGEMENT WITH STAKEHOLDERS



Sent

13.7M
E-MAILS

to stakeholders on COVID-19 topics

RESPONDED TO:

337,000
E-MAIL & PHONE
QUERIES

from patients, health care personnel, industry, & others

HOSTED

39
COVID-RELATED
WEBINARS

TOWNHALLS WITH

&

36,000+
PARTICIPANTS