FY 2020

MCMi PROGRAM UPDATE

FDA MEDICAL COUNTERMEASURES INITIATIVE

Contents

List of Tables

List of Boxes

BACKGROUND

The United States (U.S.) Food and Drug Administration (FDA) plays a critical role in protecting the U.S. from chemical, biological, radiological, nuclear (CBRN), and emerging infectious disease threats such as SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). FDA is responsible for reviewing the safety and effectiveness of **medical countermeasures** (MCMs)—including drugs, therapeutic biologics, vaccines, and devices, such as diagnostic tests—to counter these threats.[a]

In addition to its regulatory responsibilities, FDA works closely with interagency partners through the U.S. Department of Health and Human Services (HHS) **Public Health Emergency Medical Countermeasures Enterprise** (PHEMCE) to build and sustain the MCM programs necessary to effectively respond to public health emergencies.[b] This includes the agency's unprecedented COVID-19 pandemic response efforts that began in December 2019, and continue today (***see COVID-19 Response***). FDA also works closely with the U.S. Department of Defense (DoD) to facilitate the development and availability of MCMs to support the unique needs of American military personnel, including under a framework established in FY 2018 under Public Law 115-92 for enhanced FDA/ DoD collaborations. FDA supports the PHEMCE and DoD by providing subject-matter expertise in MCM development and by providing scientific and regulatory input to inform MCM development, procurement, and stockpiling decisions. In addition, FDA facilitates access to available MCMs to respond to public health and military emergencies, even when products are still investigational or not yet approved for that particular use, provided certain criteria are met.[c,d]

[a] MCMs include qualified countermeasures as defined in section 319F–1(a)(2)(A) of the Public Health Service Act (PHS Act) (42 USC. § 247d–6a(a))(2)(A); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 USC. § 247d–6d(i)(7)); and security countermeasures as defined in section 319F-2(c)(1)(B) of the PHS Act (42 USC § 247d–6b(c)(1)(B)). Some items included in this report, such as traumatic brain injury (TBI) diagnostics and some activities discussed, such as combatting antimicrobial resistance, may not meet the statutory definition of MCMs or relate directly to products defined as MCMs, but were included in this report as examples of additional work supported by MCMi Program staff because of its connection to public health preparedness. Inclusion of such examples is not intended as comprehensive reporting on Agency activities related to these topics.

[b] Section 2811-1 of the PHS Act [42 U.S.C. 300hh-10a]

[c] See e.g., sections 561 and 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

[d] For purposes of this document, "approved" refers to "FDA-approved, licensed, or cleared" under sections 505, 510(k), 512, 515, or 571 of the FD&C Act or section 351 of the PHS Act.

In 2010, FDA launched its Medical Countermeasures Initiative (**MCMi**) Program, building on the substantive MCM work ongoing at FDA and focusing increased resources on promoting the development of MCMs by establishing clear regulatory pathways for MCMs, instituting effective regulatory policies and mechanisms to facilitate timely access to available MCMs, and advancing MCM regulatory science to create the tools that support timely regulatory decision-making.

Many of FDA's activities under the MCMi Program foster the development and availability of MCMs and authorities to enable FDA to more effectively support preparedness and response efforts have been codified.[1] The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (**PAHPRA**)[e] requires FDA to issue an annual report detailing its MCM activities. This report responds to that requirement for fiscal year (FY) 2020 (October 1, 2019 – September 30, 2020).[2]

FY 2020 RESOURCES FOR MCM ACTIVITIES

Table 1: FY 2020 resources obligated to MCM activities (dollars in millions)

	FY 20 Estimate	FY 20 FTE Estimate
CBRN Base Funding	$77.8	104.5
Pandemic Influenza Base Funding	$35.9	176
MCMi Base Funding	$31.5	96.5
Subtotal	**$145.2**	**377**
COVID-19 Supplemental Funding	$48.1	2
Total	**$193.3**	**379**

FDA obligated an estimated $193.3 million in FY 2020 to support CBRN, COVID-19, and pandemic influenza-related MCM activities (***Table 1***). These resources comprised a combination of base funding and no-year funding. This funding supported 379 full-time equivalents (FTEs).

[e] Public Law 113-5, 127 Stat. 161.

OBJECTIVES, ACTIVITIES & ACHIEVEMENTS

FDA's overarching objective with respect to MCMs—which cuts across all FDA centers and offices engaged in the MCM mission space—is to facilitate the timely development of and access to safe and effective MCMs to counter CBRN and emerging infectious disease threats for civilian populations, as well as MCMs to support American military personnel.[f]

The following sections provide detail on achievements in FY 2020 with respect to these activities.

Box 1: Key FDA activities to facilitate development of and access to MCMs

Providing **regulatory advice, guidance, and technical assistance** to sponsors developing investigational MCMs for CBRN or emerging infectious disease threat indications
Discussing questions with potential product sponsors to help **clarify requirements** for approval[g] or Emergency Use Authorization (EUA)
Reviewing MCM marketing applications and **approving** those that meet standards for approval
Supporting the establishment and sustainment of an adequate **supply** of MCMs
Enabling **access** to available MCMs that are not yet approved for use—when necessary—through an appropriate regulatory mechanism, such as EUA
Responding to **emerging and re-emerging public health threats**
Establishing and sustaining Public Health and Security **Action Teams** to identify and catalyze the resolution of regulatory and scientific challenges associated with MCMs to address high-priority threats
Developing capabilities to **monitor and assess MCMs** used during public health emergencies
Collaborating with U.S. government (USG) partners developing MCMs
Sustaining the **MCMi Regulatory Science Program** to create tools, standards, and approaches to develop and assess MCM safety, efficacy, quality, and performance
Ensuring that the FDA **regulatory and policy framework** adequately supports MCM development and enables preparedness and response activities
Sustaining the **MCMi Professional Development Program** to ensure that FDA personnel maintain the requisite skills and abilities to support the MCM mission

[f] High-priority threats identified by the Enterprise for which MCMs are needed include biological threats: *Bacillus anthracis* (anthrax); *Clostridium botulinum* toxin (botulism); emerging infectious diseases (including pandemic influenza); gram-negative organisms (*Francisella tularensis* (tularemia), Yersinia pestis (plague), *Burkholderia mallei* (glanders), *Burkholderia pseudomallei* (melioidosis), *Rickettsia prowazekii* (typhus)); multi-drug resistant *Bacillus anthracis* (MDR anthrax); variola virus (smallpox); and viral hemorrhagic fevers (Marburg and Ebola); chemical threats including: nerve agents and cyanide; radiological agents (e.g., radiological dispersal devices); and nuclear agents. See the *2017-2018 PHEMCE Strategy and Implementation Plan* for more information at: **https://www.phe.gov/Preparedness/mcm/phemce/Documents/2017-phemce-sip.pdf** (see Box 1, page 8).

[g] For medical devices, the term "approval" will be used generally to mean marketing under a premarket approval application (PMA), 510(k) notification, or De Novo classification.

COVID-19 RESPONSE

The COVID-19 pandemic is unprecedented in modern history and has required an extraordinary response around the world. On January 31, 2020, the HHS Secretary issued a determination[3] that a public health emergency exists, and the World Health Organization (WHO) declared COVID-19 a worldwide pandemic on March 11, 2020—the first pandemic caused by a coronavirus.[4] Since December 2019, and throughout the remainder of FY 2020—and beyond—FDA has been "all hands on deck," with thousands of FDA scientists, clinicians, lawyers, and other experts working around the clock to respond to COVID-19.

While FDA's work continues, this report offers a snapshot of response activities during the FY 2020 reporting period, through September 30, 2020.[5] FDA's COVID-19 response actions in FY 2020 include:

Facilitating development of MCMs to diagnose, prevent, or treat COVID-19, including by working with medical product sponsors to clarify regulatory and data requirements necessary to rapidly advance development of products essential to supporting response efforts.

- Under the **Coronavirus Treatment Acceleration Program** (CTAP), a special emergency program **launched** in April 2020 for possible coronavirus therapies, FDA actively engaged with more than 2,800 medical product developers on more than 550 drug development programs, and reviewed more than 350 clinical trials.[6]
- FDA enabled more than 330 studies of potentially effective medical products to proceed, including sending 263 "safe to proceed" letters in response to IND application requests for drugs, and 76 in response to biologics products.
- FDA issued 40 **guidance documents** related to medical product development and availability for COVID-19.[7]

Enabling access to investigational MCMs and accurate and reliable tests through an appropriate mechanism, such as **Emergency Use Authorization** (EUA) or Investigational New Drug (IND).[8] FDA issued 287 EUAs enabling the use of more than 575 medical products to support the COVID-19 response in FY 2020.

- To provide regulatory flexibility for medical devices, FDA's Center for Devices and Radiological Health (**CDRH**) published 10 EUA templates, and 23 guidance documents.[9]
- FDA approved over 7,600 emergency IND requests to enable access to investigational medical products, such as convalescent plasma.

Table 2: COVID-19 EUA and Pre-EUA requests received as of September 30, 2020[10]

Product type	Pre-EUA submissions[h]	EUA submissions
Diagnostics	741	1,130
Other devices	1,147	2,214
Drugs	3	50
Biologics	7	1

Table 3: COVID-19 IND and Pre-IND requests received as of September 30, 2020

Product type	Pre-IND submissions	IND submissions
Drugs	522	348
Vaccines	65	27
Hyperimmune plasma	4	1

[h] Consistent with the guidance for industry and investigators, COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products, May 2020, the Agency has recommended that sponsors initiate COVID-19 drug development discussions under a pre-IND meeting request instead of a pre-EUA request.

Table 4: COVID-19 EUAs issued as of September 30, 2020		
Product type	**Number of EUAs**	**Enabled access to medical products**
Diagnostic devices	233	260+
Personal protective equipment (PPE), such as respirators, gowns, surgical masks	11	200+
Other devices, including ventilators	37	130+
Drugs and biological products	6	6

Actively monitoring the medical product and food supply chains to address imbalances. FDA continues to screen and monitor millions of domestic and international products in the medical supply chain to help ensure COVID-19-related supplies coming into the U.S. are safe and distributed appropriately.

- Contacted U.S. and global manufacturers to **assess supply chain vulnerabilities**, identify potential supply chain issues early, and minimize disruptions.[11] CDRH alone contacted more than 1,000 medical device manufacturing sites in 12 countries.
- Conducted supply chain illumination to identify weaknesses in obtaining and distributing needed PPE and other medical products.
- Gathered data from distributors and other third parties to monitor the supply chain to look for early signs of medical product availability issues and to determine when to implement mitigations.
- Worked with other agencies to monitor and address product shortages.
- Provided conservation strategies to health care providers to minimize the use of certain PPE to make the most of the supply and avoid running out of critical products.
- Cleared 53 PPE 510(k)s to increase the amount of PPE available in the market during the COVID-19 response
- Provided **flexibility** to the food industry to support the food supply chain and meet consumer demand during COVID-19,[12] including **establishing** a Memorandum of Understanding (MOU) with the U.S. Department of Agriculture (USDA) to strengthen U.S. food supply chain protections.[13]
- Issued 13 guidance documents to help protect the medical product supply and sustainment of the food supply for humans and animals.
- Participated in interagency efforts to address medical supply chain challenges, such as through the Federal Emergency Management Agency (FEMA)- and DoD-led Supply Chain Task Force and FEMA- and HHS-led international medical product donation efforts.
- In response to an August 2020 Executive Order,[14] FDA **identified a list** of essential medicines, MCMs, and critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. The goal of this work is to ensure the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological, and nuclear threats.[15]

Protecting the safety of the nation's blood supply and human cells, tissues, and cellular/tissue-based products for transplantation (HCT/Ps).

- Issued three guidance documents to support the urgent need for blood during the pandemic while still protecting the nation's blood supply.

Protecting consumers against fraudulent products. Unfortunately, during emergency situations, fraudulent products claiming to prevent, treat or cure conditions associated with the emergency almost always appear for sale. The FDA monitors for fraudulent products and false product claims related to

COVID-19 and other conditions and takes appropriate action to **protect patients and consumers**.[16]

- To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020.
- In FY 2020, FDA identified more than 1,000 fraudulent and unproven medical products related to COVID-19, reviewed thousands of websites, social media posts, and online marketplace listings, resulting in 114 **warning letters** to sellers, more than 223 reports sent to online marketplaces, and more than 271 abuse complaints sent to domain registrars.[17]
- FDA also identified more than 200 hand sanitizer products that consumers should not use due to contamination with methanol or 1-propanol, or because it was packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested.[18]

Conducting and collaborating on regulatory science research to help ensure FDA's ability to quickly assess safety and efficacy of new Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) MCMs, and to help diagnostic test developers validate and ensure the quality and performance of their tests.

Visit www.fda.gov/handsanitizerlist to see which hand sanitizers are on FDA's "Do Not Use" list.

- FDA developed and provided a **reference panel** to device developers as an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical, not research, purposes. The FDA panel is available to commercial and laboratory developers who are interacting with the FDA through the pre-EUA process.[19]
- FDA awarded extramural research contracts to potentially help inform development and evaluation of COVID-19 MCMs, including a contract to **Stanford University** to perform an in-depth analysis of tissue samples to learn more about how SARS-CoV-2 affects different systems in the body, and identify immune correlates,[20] and a contract to the **University of Liverpool** to analyze coronavirus samples.[21]
- FDA also expanded existing extramural research contracts to include SARS-CoV-2 research, including:
  - Public Health England's **Developing a Toolkit to Assess Efficacy of Ebola Vaccines and Therapeutics** and **Comparison of Host Responses to Ebola Virus Disease (EVD)** projects. The work is providing important insight into viral genetic diversity, impact of *in vitro* growth conditions and vaccine vector expression. Additionally, the projects are characterizing immune responses in animal models (including those co-infected with influenza) and infected individuals.
  - Stanford University's **Survivor Studies: Better Understanding Ebola's After-Effects to Help Find New Treatments** project, to include the same innovative approaches (CyTOF mass cytometry, and multiplexed ion beam imaging [viralMIBI]) used to study Ebola and Zika to better understand viral infection and immune responses to SARS-CoV-2 in nonclinical and clinical studies.

- MCMi-funded research conducted in previous fiscal years successfully **demonstrated** the feasibility of a test approach to evaluate filtering facepiece respirator (FFR) reuse and establish testing methods for additional decontamination technologies.[22] This information was used to support **EUAs for decontamination systems**, which allow certain FFRs, when decontaminated, and when there are insufficient supplies of FFRs, to be reused by medical professionals on the front lines of the COVID-19 pandemic.[23]

Engaging with partners on innovative approaches to respond to COVID-19 as quickly and safely as possible.

- FDA is working with several partners to capture relevant real-world data, for example, clinical outcome data to identify existing drugs that demonstrate possible COVID-19 treatment approaches.[24]
- FDA also teamed with the National Institutes of Health (NIH) 3D Print Exchange and Department of Veterans Affairs (VA) Innovation Ecosystem to enhance access to critical medical products through **non-traditional manufacturing approaches**; in FY 2020, this effort matched more than 500,000 3D-printed face shields and more than 348,000 3D-printed face masks with health care providers and others in need.[25]
- FDA worked with manufacturers outside of the medical product industry to produce or increase production of needed PPE, ventilators, and other medical products, including hand sanitizer. FDA met with these third-party manufacturers to determine hurdles to producing medical products and when appropriate allowed enforcement discretion of certain regulatory requirements through an EUA or immediately in effect guidances.
- FDA partnered with the DoD and the Department of Homeland Security (DHS) to address questions about the safety of food that may have been exposed to coronavirus, specifically evaluating environmental stability of SARS-CoV-2 on food and food packaging, as well as whether the virus is infectious via oral exposure to contaminated food.
- FDA meets regularly with the U.S. Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS) to address implementation issues associated with *in vitro* diagnostic (IVD) tests made available under EUAs. The Tri-Agency Task Force for Emergency Diagnostics (**TTFED**), established in FY 2019, has met routinely since January 2020 to discuss implementation of SARS-CoV-2 IVDs.[26]

COVID-19 MCM-related actions are discussed in more detail later in this report, along with FDA's other MCM-related work during FY 2020.

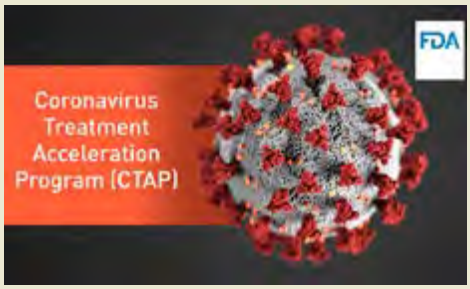
Proactive COVID-19 communication

FDA has been as transparent as possible about our COVID-19 response activities, communicating early and often with stakeholders and the American public. In early February 2020, the agency instituted a COVID-19 Joint Information Center, or JIC, a task force of more than 100 communication professionals from across the agency responsible for coordinating FDA's response-related communications. FDA launched a frequently updated **COVID-19 response page** on January 27, 2020, and the FDA COVID-19 JIC published more than 150 new response-related web pages in FY 2020.[27] Other FDA communications in FY 2020 include:

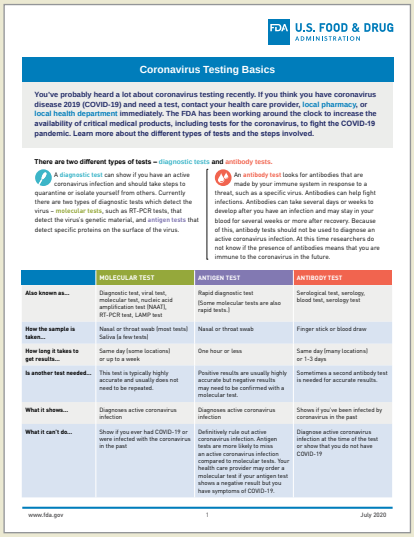
- Issuing more than 220 COVID-19 **press announcements**, including 130+ COVID-19 Daily Roundup press releases.[28]
- FDA leadership and scientific and policy experts **speaking** at hundreds of—mostly virtual—stakeholder, consumer, media, Congressional, and other events on various aspects of FDA's COVID-19 response efforts.[29]
- Publishing consumer-friendly information in plain language, including nine **Consumer Updates**,[30] 10 **videos**,[31] 19 **FDA Voices**

perspectives from FDA leadership,[32] thousands of **social media** posts,[33] weekly consumer email updates[34] featuring COVID-19 frequently asked questions, and nine COVID-19-related episodes of a new podcast, **FDA Insight**.[35] Consumer-focused information, including regularly updated **COVID-19 frequently asked questions**,[36] is available in **multiple languages** including Spanish, Simplified Chinese, Korean, Vietnamese, Tagalog, Hmoob (Hmong), and Af Soomaali (Somali).[37]

- Continually communicating with stakeholders via email, including COVID-19 response recap **emails** twice weekly, and hundreds of topic- and center-specific emails.[38] FDA also published a variety of COVID-19 educational resources, including a **patient outreach toolkit** for health care providers tailored for diverse consumers, available in English and Spanish.[39]
- Responding to more than 15,000 inquiries to the CDER Division of Drug Information, including 7,500+ from industry, 5,800+ from consumers, and 1,700+ from health care providers, with questions on a variety of drug-related topics, including hand sanitizer safety and use.
- Responding to more than 337,000 email and phone inquiries from diagnostic test developers, health care providers, and patients, including calls to a COVID-19 CDRH hotline, established in March 2020, and staffed 24/7 for several months.
- Hosting a series of webinars including a weekly **virtual town hall for SARS-CoV-2 test developers**,[40] and biweekly webinar on **respirators and other PPE for health care personnel use** during the COVID-19 pandemic.[41]
- CDRH issued several FAQs and Letters to Health Care Providers to clarify information regarding EUA medical products and other topics.[42]
- CDRH sent 13.7 million emails to stakeholders on COVID-19 topics.



Sample social media graphics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Coronavirus Testing Basics

You've probably heard a lot about coronavirus testing recently. If you think you have coronavirus disease 2019 (COVID-19) and need a test, contact your health care provider, local pharmacy, or local health department immediately. The FDA has been working around the clock to increase the availability of critical medical products, including tests for the coronavirus, to fight the COVID-19 pandemic. Learn more about the different types of tests and the steps involved.

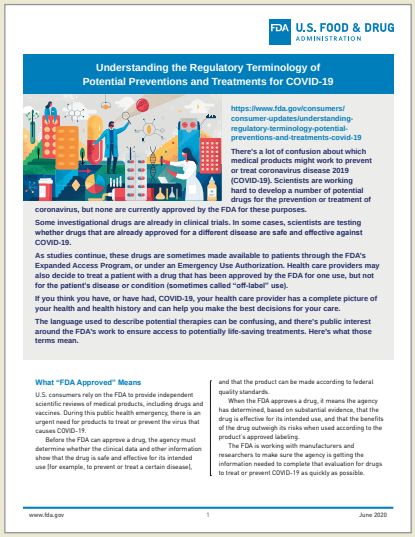
There are two different types of tests – diagnostic tests and antibody tests.

A diagnostic test can show if you have an active coronavirus infection and should take steps to quarantine or isolate yourself from others. Currently there are two types of diagnostic tests which detect the virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus.

An antibody test looks for antibodies that are made by your immune system in response to a threat, such as a specific virus. Antibodies can help fight infections. Antibodies can take several days or weeks to develop after you have an infection and may stay in your blood for several weeks or more after recovery. Because of this, antibody tests should not be used to diagnose an active coronavirus infection. At this time researchers do not know if the presence of antibodies means that you are immune to the coronavirus in the future.

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Rapid diagnostic test (Some molecular tests are also rapid tests.)	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
How long it takes to get results...	Same day (some locations) or up to a week	One hour or less	Same day (many locations) or 1-3 days
Is another test needed...	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
What it shows...	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past
What it can't do...	Show if you ever had COVID-19 or were infected with the coronavirus in the past	Definitively rule out active coronavirus infection. Antigen tests are more likely to miss an active coronavirus infection compared to molecular tests. Your health care provider may order a molecular test if your antigen test shows a negative result but you have symptoms of COVID-19.	Diagnose active coronavirus infection at the time of the test or show that you do not have COVID-19

www.fda.gov 1 July 2020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Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19

https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19

There's a lot of confusion about which medical products might work to prevent or treat coronavirus disease 2019 (COVID-19). Scientists are working hard to develop a number of potential drugs for the prevention or treatment of coronavirus, but none are currently approved by the FDA for these purposes.

Some investigational drugs are already in clinical trials. In some cases, scientists are testing whether drugs that are already approved for a different disease are safe and effective against COVID-19.

As studies continue, these drugs are sometimes made available to patients through the FDA's Expanded Access Program, or under an Emergency Use Authorization. Health care providers may also decide to treat a patient with a drug that has been approved by the FDA for one use, but not for the patient's disease or condition (sometimes called "off-label" use).

If you think you have, or have had, COVID-19, your health care provider has a complete picture of your health and health history and can help you make the best decisions for your care.

The language used to describe potential therapies can be confusing, and there's public interest around the FDA's work to ensure access to potentially life-saving treatments. Here's what those terms mean.

What "FDA Approved" Means

U.S. consumers rely on the FDA to provide independent scientific reviews of medical products, including drugs and vaccines. During this public health emergency, there is an urgent need for products to treat or prevent the virus that causes COVID-19.

Before the FDA can approve a drug, the agency must determine whether the clinical data and other information show that the drug is safe and effective for its intended use [for example, to prevent or treat a certain disease], and that the product can be made according to federal quality standards.

When the FDA approves a drug, it means the agency has determined, based on substantial evidence, that the drug is effective for its intended use, and that the benefits of the drug outweigh its risks when used according to the product's approved labeling.

The FDA is working with manufacturers and researchers to make sure the agency is getting the information needed to complete that evaluation for drugs to treat or prevent COVID-19 as quickly as possible.

www.fda.gov 1 June 2020


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FDA COVID-19 Response

At-A-Glance Summary as of July 23, 2020

The U.S. Food and Drug Administration, along with other federal, state, and local agencies and public health officials across the country, continues critical work to protect public health during the pandemic of COVID-19. Major focus areas of the FDA's response include increasing the availability of tests, therapeutics, and other devices such as ventilators and personal protective equipment, and many other important items necessary for the response. The FDA is also monitoring the human and animal food supply and taking swift action on fraudulent COVID-19 products.

Highlights of FDA Activities

Ensuring Timely Availability to Accurate and Reliable Tests

- To date, the FDA has currently authorized 187 tests under Emergency Use Authorizations (EUAs); these include 154 molecular tests, 31 antibody tests and 2 antigen tests.
- The FDA continues to monitor authorized tests and emerging scientific evidence and may revise or revoke an EUA, when appropriate, including when a test's benefits no longer outweigh its risks. The FDA provides continuous updates to make clear which tests have been issued EUAs by the agency, and which tests should not be used.

Accelerating Availability of Medical Equipment and Products for Treatment

- The FDA added more than 85 ventilators and accessories for emergency use to the ventilator EUA and issued EUAs for other equipment to treat patients during COVID-19.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- There are now more than 510 drug development programs in planning stages and as of mid-July, the agency has reviewed more than 230 trials of potential therapies for COVID-19.

Actively Monitoring the Medical Product and Food Supply Chains to Address Imbalances

- Continue to screen and monitor millions of domestic and international products in the medical supply chain to help ensure COVID-19-related supplies coming into the U.S. are safe and distributed appropriately.

Halting the Sale of Products with Fraudulent Claims Related to COVID-19

- As of June 2020, the FDA has identified more than 700 fraudulent and unproven medical products related to COVID-19.
- To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020. The Operation Quack Hack team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in over 90 warning letters to sellers, more than 150 reports sent to online marketplaces, and more than 250 abuse complaints sent to domain registrars to date.

www.fda.gov 1 July 23, 2020

A sample of print and online COVID-19 communications produced by the FDA JIC

MEDICAL COUNTERMEASURE APPROVALS

During FY 2020, FDA continued to review marketing applications for MCMs against CBRN and emerging infectious disease threats and approve safe and effective MCMs. FDA approved the majority of MCM marketing applications under review[i] in FY 2019 (***see Appendix 1: FY 2020 Medical Countermeasure Approvals – Biologics and Drugs*** and ***Appendix 2: FY 2020 Medical Countermeasure Approvals – Devices***).[43]

MCMs to treat or prevent diseases or conditions caused by CBRN threats

For radiological/nuclear agent preparedness, FDA cleared **KeraStat Cream**, for indications of radiation dermatitis. This product is designed to reduce the painful ulceration and skin damage that occurs during radiation therapy. The effectiveness of KeraStat Cream is backed by human data in patients with breast cancer, that shows that KeraStat Cream reduces the symptoms of radiation dermatitis and improves quality of life. The initial work that led to the development of KeraStat Cream was funded under a Biomedical Advanced Research and Development Authority (BARDA) contract.

MCMs to treat or prevent diseases or conditions caused by emerging infectious diseases

To support Ebola preparedness, FDA approved **Ervebo**, the first FDA-approved vaccine for the prevention of EVD, caused by *Zaire ebolavirus* in individuals 18 years of age and older.[44] Cases of EVD are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with EVD. Because of the public health importance of a vaccine to prevent EVD, FDA worked closely with the company and completed its evaluation of the safety and effectiveness of Ervebo in less than six months.

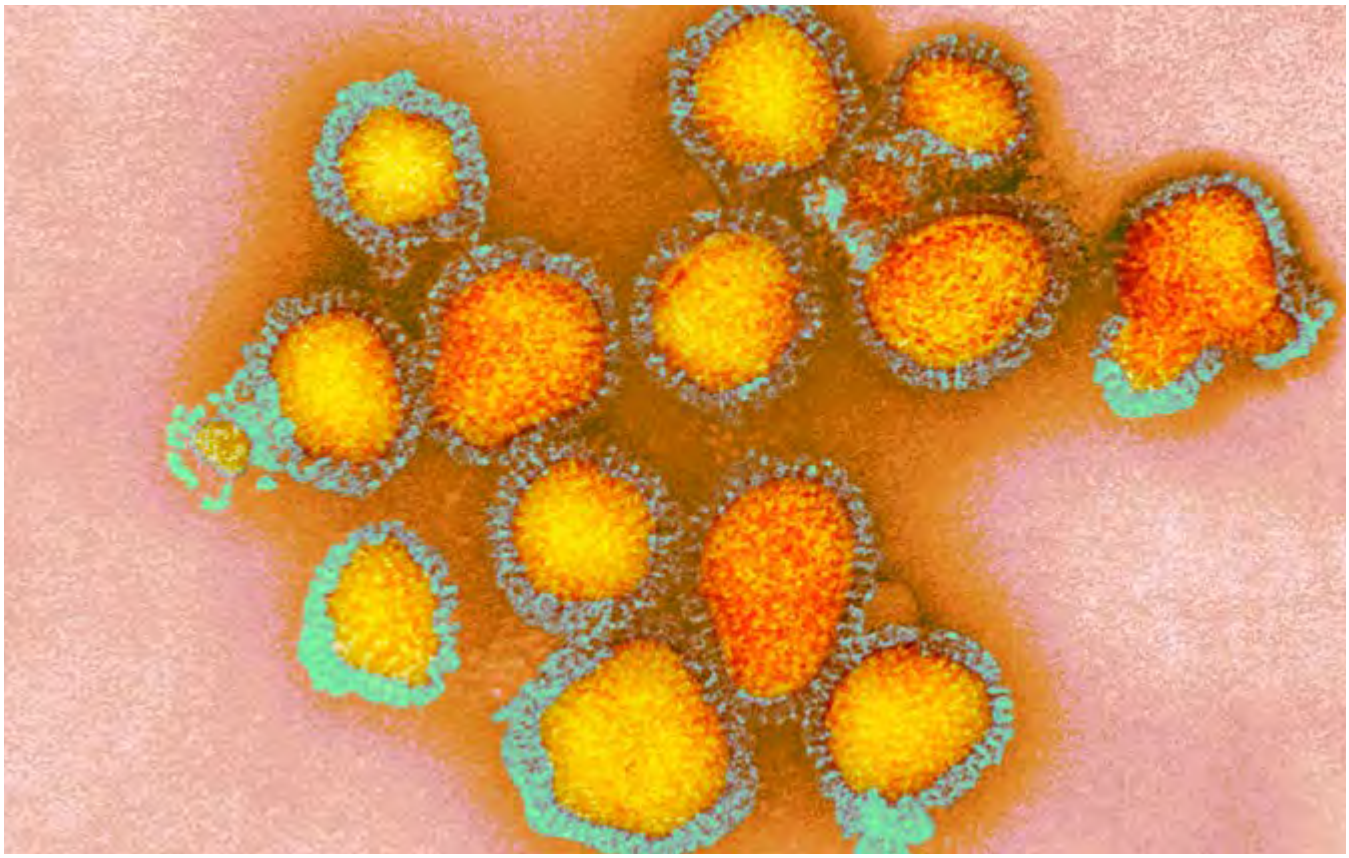
> FDA approved the first vaccine for prevention of Ebola virus disease and first rapid Ebola diagnostic test allowed to be marketed in the U.S.

Diagnostics and screening tests for CBRN threats and emerging diseases

To support anthrax preparedness, FDA cleared the ***Bacillus anthracis* Detection Kit**, a real-time polymerase chain reaction (PCR) test kit intended for the qualitative IVD detection of target DNA sequences for *B. anthracis*, the bacteria that causes anthrax. This test is indicated for use in Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified high-complexity laboratories in response to a confirmed *B. anthracis* event only in accordance with the guidelines provided by public health authorities prior to or during a public health emergency. FDA also cleared the CDC ***B. anthracis* Real-time PCR Assay**, for the qualitative detection of plasmid and chromosomal DNA sequences from *B. anthracis*.

FDA **authorized** under the De Novo premarket review pathway a rapid diagnostic test (RDT) to detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola (cadaveric oral fluid). The **OraQuick Ebola Rapid Antigen Test** is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for EVD. The test provides a rapid, presumptive diagnosis that must be confirmed.[45]

[i] For purposes of this document, "under review" indicates that a marketing application has been submitted to FDA for approval by the product's sponsor.



H3N2 influenza virus particles, colored transmission electron micrograph (TEM)

FDA cleared for marketing several diagnostic tests to detect Zika virus immunoglobulin (IgM) antibodies in human blood. FDA cleared the LIAISON XL Zika Capture IgM Assay II for the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting the CDC Zika virus clinical and/or epidemiological criteria. FDA also cleared the Chembio Diagnostics DPP Zika IgM System, which includes the DPP Zika Test Device and the DPP Micro Reader, and can use fingerstick whole blood specimens to provide a result after just 15 minutes.[46] Previously, these tests had been authorized only for emergency use under FDA's EUA authority.[47]

Pandemic influenza preparedness

FDA approved **AUDENZ**, (Influenza A (H5N1) Monovalent Vaccine, Adjuvanted) for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. AUDENZ is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine. This vaccine received accelerated approval, and will be produced and distributed under contract to the U.S. government as part of national pandemic preparedness initiatives.[48]

In FY 2019, FDA approved Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Xofluza is one of several FDA-approved antiviral drugs to treat acute uncomplicated influenza, and is the first in nearly 20 years with a novel mechanism of action.[49] In FY 2020, FDA **approved** a supplemental New

> To support pandemic influenza preparedness, FDA approved a new indication for an H5N1 influenza vaccine

Drug Application (sNDA) for Xofluza for the treatment of acute, uncomplicated influenza in people 12 years of age and older who have been symptomatic for no more than 48 hours and who are at high risk of developing flu-related complications; the sNDA provides for updates to the product labeling and patient information.

In addition, FDA approved a Biologics License Application (BLA) supplement for a four-strain (quadrivalent) version of **Fluzone high-dose influenza vaccine** for use in those age 65 and older.

FDA also cleared four new influenza tests and cleared modifications to four previously approved influenza detection IVD devices to, for example, include additional specimen types, additional instrument options, and software modifications, and update package inserts. These steps forward in influenza prevention and diagnostics facilitate preparedness for both seasonal and pandemic influenza, as new tests and technologies may be applied more rapidly to emerging pandemic influenza strains once approved for seasonal influenza use.

All-hazards preparedness

To support trauma care, including military medical needs, FDA cleared the **Protego Antimicrobial Wound Dressing**, a single-use, sterile, antimicrobial gauze dressing impregnated with a petrolatum-based wound care emulsion, providing broad-spectrum antimicrobial protection against bacteria, fungi, and yeasts.

Additional marketing applications in progress

Nine additional marketing applications for new MCMs or new MCM indications were under review in FY 2020; these reviews were still ongoing at the end of the reporting period for this report. While FDA anticipates meeting the goal date for a decision for each of these submissions, FDA is generally prohibited from disclosing any determinations regarding the filing or approvability of any marketing application for a medical product under applicable statutory and regulatory provisions unless the application is approved or other grounds for disclosure apply.[50]

SUPPORTING AN ADEQUATE SUPPLY OF MEDICAL COUNTERMEASURES

FDA continued efforts to support the establishment and sustainment of an adequate supply of MCMs during FY 2020. One way FDA does this is by supporting the **Shelf-Life Extension Program** (SLEP). SLEP is a federal fee-for-service program for extending the useful shelf life of military-significant and contingency use medical products, including MCMs that are owned by components of DoD or other federal program participants such as the **Strategic National Stockpile** (SNS). SLEP is designed to defer drug replacement costs for date-sensitive stockpiles of drugs by extending their useful shelf life beyond the manufacturer's original labeled expiration date. FDA laboratory personnel test and evaluate drugs submitted for shelf-life extension to assure stability and quality before an expiry dating extension is granted. In FY 2020, as a result of SLEP testing that assured drug stability and quality, FDA granted shelf-life extensions for approximately 1,250 lots (batches) of MCM drugs.

To help ensure an adequate supply of MCMs for potential emergencies, FDA may also extend the expiration dating of MCMs outside of SLEP based on FDA's review of scientific data.[51] For example, FDA issued final guidance to support government public health and emergency response stakeholder testing to support FDA extensions of the expiration date of specific lots of doxycycline hyclate 100 mg capsules held in strategic stockpiles for anthrax emergency preparedness and response purposes.[52] Previously issued FDA-authorized extensions under the recommendations of the draft guidance were extended through July 2022. Based on government stakeholder needs, FDA continues to review scientific data to determine whether additional extensions of other MCMs may be supported outside of SLEP. In addition, in February 2020, HHS issued a message to state stakeholders holding antiviral drug products (Tamiflu and Relenza) about additional expiry

dating extensions for properly held product. Based on FDA's review of scientific data, FDA concluded for emergency responses that, provided the products have been stored under labeled storage conditions, it is scientifically supportable for certain lots of Tamiflu 75 mg capsules held in strategic stockpiles to be used for a maximum of 15 years beyond their date of manufacture, and for certain lots of Relenza inhalation powder held in strategic stockpiles to be used for a maximum of 10 years beyond their date of manufacture.[53]

Working to resolve MCM shortages as quickly as possible when they occur is another way FDA helps ensure an adequate supply of MCMs. In addition to extensive COVID-19-related supply chain monitoring and mitigation activities, as noted on page 6, in FY 2020, FDA continued to collaborate with U.S. government partners and manufacturers of auto-injector products used for the treatment of nerve agent and insecticide poisoning to help prevent shortages of these products. FDA reviewed applicable scientific data, including through SLEP, to assess whether, if properly stored, certain lots of this manufacturer's auto-injector products held for emergency use can continue to be used beyond the original labeled expiration date for a period specified by FDA, to help ensure ready access to these products. FDA also reviewed scientific data to assess whether certain lots are no longer useable and, therefore, should be properly disposed of.[54]

FDA also responded to numerous stakeholder inquiries on nerve agent auto-injector **expiry dating extensions** to assist in determinations about whether stockpiled auto-injector products made by the same manufacturer should be retained. Meanwhile, FDA continued to work with the applicant on manufacturing issues.

ENABLING ACCESS TO MEDICAL COUNTER-MEASURES UNDER FDA'S EMERGENCY USE AUTHORIZATION AUTHORITY[j]

During FY 2020, FDA continued to work with PHEMCE partners, including DoD, and product sponsors to enable access to unapproved MCMs when necessary.[k] One way FDA does this is by issuing **Emergency Use Authorizations**. The EUA authority allows FDA to authorize the use of an unapproved medical product, or the unapproved use of an approved medical product, in anticipation of a potential emergency or during an actual emergency involving CBRN agents, or, for DoD purposes, other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces, if certain statutory criteria are met.[l] A list of **current EUAs** is published on the FDA website.

In October and November 2019, FDA amended three EUAs for Ebola diagnostic tests authorized in previous years. In May 2020, amended an EUA for Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma (FDP), to allow French FDP to be manufactured from certain French-sourced or U.S.-sourced plasma, and update the authorized EUA fact sheets and labeling to clarify the use of either plasma source, under the EUA initially granted in July 2018. In FY 2020 FDA received one non-COVID amendment request for an EUA diagnostic device, which was not granted. FDA also received 367 COVID amendment requests for EUA diagnostic devices and granted or acknowledged 198 of these requests.

In addition to issuing EUAs when necessary, FDA engages in ongoing pre-EUA submission processes by which FDA works with product sponsors or government agencies, such as the CDC and DoD, to facilitate the development of pre-EUA packages that may form the basis of an EUA request and issuance when the statutory criteria are met. During FY 2020, FDA continued to work with government partners and industry on pre-EUA activities for MCMs against a diverse array of threats, in addition to intensive COVID-19 response efforts.[m, 55]

> In FY 2020, FDA issued 275+ EUAs, enabling access to 575+ medical products to support COVID-19 response efforts

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[j] Section 564 of the FD&C Act (21 USCS § 360bbb-3)

[k] This support includes numerous activities including availability of pre-IND consultations for drug development proposals and pre-market consultations for device development proposals, advice, and feedback on clinical trial preparation, discussions related to expanded access protocols and pre-EUA discussions.

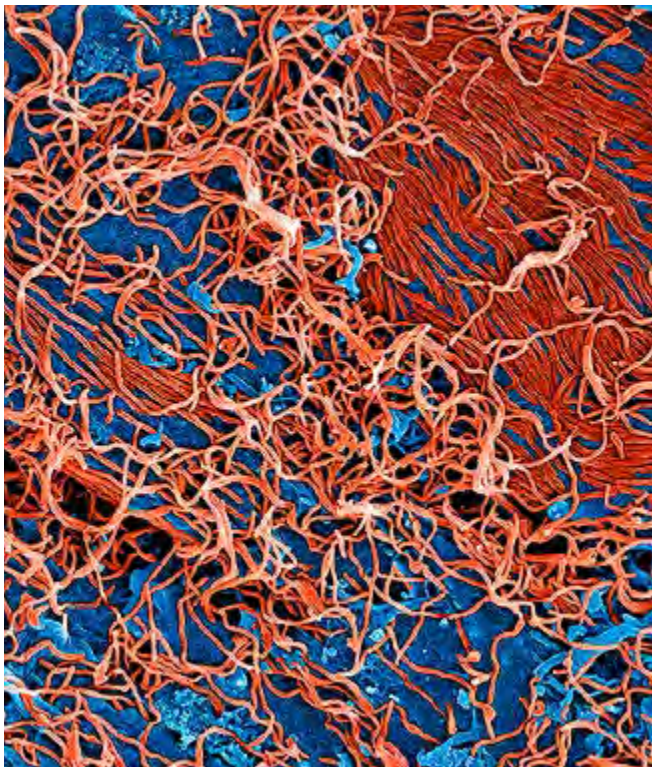
[l] The Project BioShield Act of 2004 [PL 108-276] established section 564 of the FD&C Act, granting the Secretary of HHS the authority to declare that circumstances exist that justify the authorization of "emergency use" of unapproved MCMs, or unapproved uses of approved MCMs, under certain terms and conditions. The authority to issue EUAs, after the declaration by the Secretary that issuance of such EUAs is justified, was delegated to the FDA Commissioner. Section 564 of the FD&C Act was amended by PAHPRA in 2013, the 21st Century Cures Act (Cures Act) in 2016 [PL 114-255], and PL 115-92 in 2017.

[m] A pre-EUA package contains data and information about the safety, quality, and efficacy of the product, its intended use under an EUA, and information about the potential emergency situation that might unfold. The pre-EUA process allows FDA scientific and technical subject matter experts to begin a review of information and assist with the development of conditions of authorization, fact sheets, and other documentation needed for an EUA in advance of an emergency. For more information about EUAs, see Emergency Use Authorization of Medical Products and Related Authorities at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities**

RESPONDING TO EMERGING INFECTIOUS DISEASE PUBLIC HEALTH THREATS

During infectious disease outbreak and epidemic responses, FDA works proactively with U.S. government partners, medical product developers, and international partners (including the WHO and regulatory counterparts) to provide scientific and regulatory advice to help facilitate the development and availability of MCMs.

In addition to responding to specific threats, including COVID-19 and Ebola, FDA also engages in numerous activities to support public health emergency preparedness for a variety of threats. In addition to COVID-19 response activities noted on page 5, emerging infectious disease-specific response activities in FY 2020 included:



Filamentous Ebola virus particles (colored red) budding from a chronically infected VERO E6 cell (colored blue)

Ebola

FDA continued to support the international response to outbreaks of Ebola virus disease, including follow-up activities related to the 2014-2016 West Africa outbreak and ongoing response to the most recent Democratic Republic of the Congo (DRC) outbreak continuing into 2020. In FY 2020, FDA:

- Continued to work closely with interagency partners, medical product developers, the WHO, and international regulatory counterparts to help move candidate medical products for Ebola forward in development as quickly as possible. For example, FDA participated in discussions of potential clinical trial approaches including a trial comparing several investigational therapeutics against a control arm that began in 2018 and issued preliminary results in 2019.[56] Based on preliminary findings in this NIH trial, FDA continues to provide regulatory guidance to product developers.[57] FDA also provided to WHO study recommendations for the evaluation of rapid Ebola antigen-based diagnostic tests to facilitate data collection for future marketing submissions.
- Continued work to facilitate access to available medical products through appropriate regulatory mechanisms when necessary and to protect consumers from fraudulent products and false product claims related to Ebola. As noted above, in December 2019, the first FDA-approved vaccine for prevention of EVD was licensed.
- Continued to work with manufacturers of authorized Ebola diagnostics to make rapid tests available, as well as advance these products toward market approval. As noted above, in October 2019, FDA allowed marketing in the U.S. of the first rapid diagnostic test to detect Ebola virus antigens.
- Funded new extramural research to expand a biobank of plasma and peripheral blood mononuclear cell (PBMC) samples to help support the development of MCMs against Ebola virus. (Also see ***Medical Countermeasure Regulatory Science***)

Box 2: Key FDA emerging threat response activities
Collaborating closely with HHS, other federal agencies, and international partners in preparedness and response decisions regarding MCM development and use
Providing **review and feedback** on development proposals including clinical trial design and data assessment
Maintaining contact with drug, vaccine, and device (including diagnostic test) developers, and **expediting the regulatory review** of data for products that are currently in the pipeline and products that are still very early in development
Advising on design and set-up of **clinical trials** for establishing the safety and efficacy of investigational products for the treatment and/or prevention of emerging infectious diseases, including COVID-19, Ebola and Zika
Supporting FDA's ongoing efforts to **protect the safety of the nation's blood supply** and HCT/Ps for transplantation
Enabling **access to investigational MCMs**—when necessary—through an appropriate mechanism such as under an expanded access protocol or under an EUA, including review of expanded access protocols that may be used in Ebola outbreaks when a suitable clinical trial is not available, and updating EUA information for Zika and Ebola diagnostics that have not yet met requirements for full marketing clearance
Issuing EUAs as needed, including authorizing use of a freeze-dried plasma product and a rapid Ebola diagnostic test with a battery-operated portable reader
Addressing issues related to the **import and export** of investigational MCMs
Preparing to implement **safety surveillance** programs for adverse events associated with MCM use and take appropriate action if safety issues are identified
Monitoring the **MCM supply chain** to identify product shortages and distribution of misbranded/counterfeit products
Monitoring **false product claims**, and taking appropriate action when necessary to protect consumers

Zika

FDA also continued to actively support the national and international **response to Zika virus**. In FY 2020, FDA cleared for marketing several diagnostic tests to detect Zika virus IgM antibodies in human blood (see ***Diagnostics and screening tests for CBRN threats and emerging diseases***), and continued to work with Zika diagnostic manufacturers to help advance additional Zika diagnostics toward market approval. FDA also **published** information about how an FDA Zika virus reference panel for molecular-based diagnostic devices supported product testing for EUA and 510(k) submissions.[58]

MERS-CoV

FDA continued activities to respond to the Middle East Respiratory Syndrome coronavirus (MERS-CoV) outbreak, which was first observed in the Middle East in 2012, with subsequent importations by international travel into a number of other countries. FDA continues to work with manufacturers toward making more MERS-CoV IVD tests available.

ACTION TEAMS

Under the MCMi Program, FDA established multidisciplinary Public Health and Security Action Teams (Action Teams) as necessary to advance MCMs for priority threats by working with internal and external entities—as appropriate—to identify and catalyze the resolution of regulatory and scientific challenges to MCM development. The following information summarizes activities of the Action Teams that were active in FY 2020.

Microbial Sequencing and Multiplex *In Vitro* Diagnostics Action Team

This Action Team continued its work to support sequence-based diagnostic device development. Such diagnostics may include multiplex diagnostic devices, which test for multiple pathogens simultaneously from a single clinical specimen, providing valuable information when responding to a public health emergency.

Key activities during FY 2020 included:

- Continuing collaboration with the National Center for Biotechnology Information (NCBI), the Lawrence Livermore National Laboratory (LLNL), and the Institute for Genome Sciences at the University of Maryland to establish quality criteria for microbial reference databases that will be critical to developers seeking to validate their candidate next-generation sequencing (NGS)-based IVD tests.
- Continuing to facilitate the population of a publicly available **database** for reference-grade microbial genomic sequences (FDA Database for Regulatory Grade Microbial Sequences, or **FDA-ARGOS**).[n] In April 2020, **SARS-CoV-2 reference-grade sequence data** was added to the FDA-ARGOS database.[59]
- Continuing collaboration with the National Institute of Standards and Technology (NIST) to develop mixed microbial reference materials that will be critical to developers seeking to validate their candidate NGS-based IVD tests, and produce both microbial and human reference genome samples and materials to support the development and validation of NGS instrumentation/software platforms for sequencing microorganism and human nucleic acids.
- Sustaining an interactive collaboration with DoD on the development of its Next-Generation Diagnostic System (NGDS Increment II).

FDA/DoD Enhanced Engagement Action Team

This Action Team[60] continued its efforts to facilitate the development and regulatory assessment of MCMs and related technologies primarily to support U.S. military personnel and trauma victims. Key FY 2020 activities included:

- Working with DoD partners to support COVID-19 response efforts, including:
  - The Joint Rapid Acquisition Cell–Screening and Diagnostics Capability (JRAC-SDC) to assist shortage analysis supporting diagnostics industrial base expansion efforts for HHS and the DoD Clinical Laboratory Supply Working Group to understand critical clinical lab supplies, reagents, and consumables currently in short supply as a result of SARS-CoV-2.

[n] FDA-ARGOS was established in FY 2014, through NCBI, to sequence approximately 2,000 isolates. This database is being expanded to generate 150 high-quality, nearly complete draft genome sequences of mosquito-borne viral pathogens, including Zika virus sequences. As part of this project, FDA set up collaborations to acquire the following prospective samples: 1) clinical isolates from Children's Hospital and George Washington University in Washington, D.C., to enhance diversity of GenBank, 2) biothreat and near-neighbor isolates/gDNA from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)/Critical Reagents Program (CRP), 3) Ebola isolates/gDNA from Public Health Canada/National Institute of Allergy and Infectious Diseases (NIAID) collaboration and USAMRIID/CRP, 4) antimicrobial resistance (AMR) isolates from Children's Hospital, and 5) difficult-to-acquire isolates from the American Type Culture Collection (ATCC). The FDA-ARGOS database is available at **https://www.ncbi.nlm.nih.gov/bioproject/231221**

- The use of EUA diagnostic tests, 3D printing of medical products, PPE, and ventilators.
- With the U.S. Army Medical Research and Development Command's (USAMRDC) Telemedicine and Advanced Technology Research Center (TATRC), supporting the rapid development, deployment and testing of the National Emergency Telecritical Care Network (NETCCN) to support the COVID-19 response. TATRC conducted a three-day meeting in September 2020 regarding NETCCN. FDA staff participated as a speaker and panelist.

- Continuing a joint program to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel. (See ***Enhanced FDA/DoD Collaborations for details***.)
- Meeting with DoD offices, commands, and programs to discuss regulatory and scientific issues related to developing and providing access to medical products for the warfighter.
- Assisting DoD on potential approaches for addressing the unique challenges in conducting studies or making MCMs available for the warfighter. Focus areas include traumatic injury (including traumatic brain injury [TBI]), hemorrhage, nerve agents, and autonomous systems.
- Continuing a formal fellowship program between FDA and DoD to support the training of DoD scientific and medical personnel in medical product development and FDA's regulatory processes. Two DoD laboratory experts are currently being cross-trained in regulatory review at FDA.
- Discussing the development of autonomous systems and closed-loop control technologies in medical care . As part of a continued collaboration between FDA and DoD on the development of autonomous systems, FDA and Joint Program Committee-1/Medical Simulation and Information Sciences (JPC-1/MSIS) held a meeting in January 2020 with members from the various military branches.
- Sharing regulatory considerations and updates on additive manufacturing. FDA and the U.S. Army Medical Logistics Command conducted a meeting on additive manufacturing of medical devices and medical device components, and continuing regular discussions on this topic.

Acute Radiation Syndrome (ARS) Action Team

This Action Team continued its efforts to clarify the regulatory requirements for development of radiological/nuclear (rad/nuc) MCMs, which include products for improving survival and mitigating or treating injuries from rad/nuc events, and products for determining subject exposures in a nuclear detonation.
Key activities during FY 2020 included:

- Facilitating cross-agency interaction and supporting FDA rad/nuc MCM activities. In FY 2020, FDA hosted a meeting with NIAID to discuss lung model development for MCMs against radiation-induced lung injuries.
- Continuing interaction with BARDA and NIAID to address issues and challenges related to development of radiation biodosimetry medical devices.

- Interacting with NIAID on MCM development for radiation-induced thrombocytopenia. Continuing to provide regulatory input on the HHS Assistant Secretary of Preparedness and Response (ASPR) radiation emergency medical management guidance document for myeloid cytokine treatment of acute exposure to myelosuppressive doses of radiation (H-ARS).
- Sharing with FDA reviewers the latest scientific research related to rad/nuc cellular therapy development and discussing issues and challenges in development of products for cutaneous radiation injuries.

REGULATORY ADVICE AND GUIDANCE

During FY 2020, FDA continued to provide regulatory advice and guidance to sponsors and applicants of MCMs and our federal partners funding MCM development, to help foster the development and availability of various MCMs. FDA provides regulatory advice and guidance through a variety of mechanisms including direct engagement with sponsors and applicants, issuing **guidance documents**, and holding **Advisory Committee** meetings and public workshops. As noted on page 5, FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. In FY 2020, FDA issued 62 **guidance documents** to provide updated policies, transparency, and regulatory flexibility to address the vital medical products and public health issues facing the U.S. during this pandemic. These guidances are on diagnostics, PPE, ventilators, other medical devices, investigational treatment with convalescent plasma, conduct of clinical trials of medical products, blood supply, hand sanitizers, food safety and supply, and other topics.[61]

> FDA issued more than 60 guidance documents in FY 2020 to provide updated policies, transparency, and regulatory flexibility during COVID-19

FDA medical product review centers engage with MCM sponsors and applicants throughout the product life cycle. For example, FDA reviews IND applications and Investigational Device Exemptions (IDEs) and responds to questions from sponsors, applicants, and federal agencies supporting product development. FDA medical product review centers have extensive interactions to discuss testing, data requirements, and nonclinical development plans to move candidate

MCMs into clinical development and assess progress as these specialized product candidates move through clinical development toward a marketing application. FDA also continues to engage with sponsors and applicants to address any issues that arise during regulatory review as well as during the post-marketing phase for these MCMs.

FDA has established policies and procedures for conducting formal meetings with product sponsors or applicants. For detailed information on meetings about product development with the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), see the revised draft guidance **Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products**.[62] Formal meetings are held—as needed—at the request of a product sponsor or applicant, and requests for meetings are granted unless there is a substantive reason for denying the request (e.g., the product for which the meeting is requested is not sufficiently developed to warrant the type of meeting sought).[o] When FDA denies a request for a meeting, the sponsor or applicant is provided feedback on steps required to warrant a meeting.

CBER and CDER categorize formal meetings with product sponsors and applicants as Type A, B, and C. Type A meetings are meetings to help an otherwise stalled product development program proceed (such as a dispute resolution meeting, a meeting to discuss a clinical hold,[p] and a Special Protocol Assessment (SPA) meeting[63]).

Type B meetings are meetings held at pivotal points during product development to help products move into and through clinical development to marketing application (i.e., pre-IND application meetings, certain end-of-phase 1 meetings, end-of-phase 2/pre-phase 3 meetings, and pre-New Drug Application (NDA)/BLA). Type B meetings also include pre-EUA meetings, Risk Evaluation and Mitigation Strategies (REMS) meetings, and certain meetings for breakthrough therapy-designated products, as explained in the revised draft guidance Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.

Type C meetings are any meetings other than a Type A or Type B meeting, and can address a range of issues related to product development (e.g., discussions related to data requirements, scientific issues related to product development and manufacturing, post-marketing commitments or requirements, etc.). Meetings that are not categorized as Type A, B, or C are non-PDUFA meetings such as meetings on a sponsor's compliance status or follow-up on post-marketing commitments.

To provide general considerations to assist sponsors in preparing pre-IND meeting requests for COVID-19 related drugs for the duration of the COVID-19 public health emergency, in May 2020, FDA issued the guidance **COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and**

[o] Formal meetings may also be rescheduled or canceled based on criteria described in FDA guidance.

[p] A clinical hold is an order issued by FDA to a product sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. See 21 CFR 312.42 for more information on clinical holds.

Biological Products.[64] As described in further detail in this guidance, FDA recommends that sponsors initiate all drug development interactions for COVID-19 related drugs through IND meeting requests.

In FY 2020, CBER held 10 formal meetings with MCM sponsors or applicants and 36 other (non-PDUFA) meetings, and CDER held 21 formal meetings (***Table 5***) and 43 other (non-PDUFA) meetings.

CDRH categorizes its formal meetings with product sponsors as Pre-Submission (Pre-sub) and 510(k)/Premarket Approval (PMA) Submission meetings. Pre-sub meetings are designed for FDA staff to provide feedback in response to specific questions related to product development, including planned nonclinical evaluations, proposed clinical study protocols, regulatory pathways, or data analysis recommendations prior to making a submission.

CDRH reviewed 54 Pre-subs and 146 Submissions (marketing submissions) for MCM medical devices in FY 2020. FDA provided extensive written feedback on the Pre-subs, and many of these sponsors elected to cancel additional formal follow-up meetings after receiving this information, as they did not see the need for the originally requested formal meeting. If the sponsor wanted to further discuss the written Pre-sub feedback, a formal Pre-sub meeting was held. Submission issue meetings are sometimes held to discuss deficiencies identified during premarket review of device marketing applications and to provide clarification of FDA's questions or to discuss an approach to address any complex issues identified. In FY 2020, CDRH provided written feedback for 29 MCM Pre-sub or Submission applications and held 42 formal Pre-sub and three formal Submission meetings with MCM sponsors or applicants (***Table 6***).

Table 5: FY 2020 formal meetings between CBER/CDER and MCM sponsors or applicants

Meeting Type	CBER	CDER
Type A	0	0
Type B	7	16
Type C	3	5
Total	**10**	**21**

Table 6: FY 2020 formal meetings between CDRH and MCM sponsors or applicants

Meeting Type	CDRH
Pre-Submission	42
Submission	3
Total	**45**

In addition to the marketing applications discussed in the previous paragraph, CDRH had significant interactions with MCM sponsors during the pre-EUA and EUA Interactive Review process. The **Interactive Review** process was developed to facilitate the efficient and timely review and evaluation of pre-EUA and EUA submissions through increased interaction between FDA and sponsors, including the exchange of scientific and regulatory information.[65] In FY 2020, CDRH reviewed and provided written feedback on 1,888 pre-EUAs and 3,344 EUA submissions, with many submissions involving multiple rounds of written feedback provided during interactive review, and held 1,086 pre-EUA and EUA meetings (telecons).

FDA also issued in May 2020 a guidance document, **Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers**[66] for drugs and biologics, and in June 2020, **Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers**.[67]

In addition, eligible MCM sponsors or applicants can request a Regulatory Management Plan (RMP), setting forth a process whereby the terms for inter-

actions between FDA and the product sponsor or applicant can be delineated.[q] In December 2019, FDA published a new web page, **Availability of Regulatory Management Plans**, to provide information about RMPs for MCM sponsors or applicants.[68] FDA did not receive any written MCM-related RMP requests in FY 2020.

FDA also conducted enhanced inspection and compliance activities to support early identification of any problems that might impede MCM product development. FDA provided technical advice to minimize risk during MCM product manufacturing, including pre-approval inspections or site visits to ensure that manufacturing establishments are capable of adequately manufacturing MCM products, and that submitted application data are accurate.

In addition to its direct work with MCM sponsors and applicants, FDA also issues guidance documents that help foster MCM development and availability.[r] Guidance documents issued during FY 2020 directly related or applicable to MCMs policies or regulatory issues are listed in ***Appendix 3: MCM-Related Guidance Issued in FY 2020***.

FDA also holds Advisory Committee meetings and public workshops to obtain independent input and expert advice on scientific, technical, and policy matters to facilitate MCM development. Key meetings and public workshops held during FY 2020 are listed in ***Appendix 4: Key MCM-Related Meetings Held in FY 2020***. In addition to these FDA-hosted meetings, FDA experts continued to participate in and present at a wide variety of other meetings, workshops, and conferences.[69, 70]

COLLABORATION AND COMMUNICATION

During FY 2020, FDA continued to **collaborate** extensively with PHEMCE and DoD (more on page 25) partners to foster the development and availability of MCMs. FDA provided subject matter expertise and technical assistance to approximately 73 standing interagency and PHEMCE- and DoD-specific committees and working groups that develop MCM requirements, plans, priorities, and policies and conduct program oversight and integration. These standing committees and working groups met on a weekly, monthly, bimonthly, quarterly, semi-annually, or as-needed basis depending on the requirements of the issues at hand. These committees and working groups addressed a range of topics across the full spectrum of activities associated with MCMs including threat assessment, requirements setting, product development, procurement, stockpiling, utilization, and **monitoring and assessment** of MCMs after they have been dispensed or administered. In addition, FDA supported PHEMCE partners by providing subject matter expertise for various MCM-related proposal reviews. FDA also continues to support implementation of the 2018 **National Biodefense Strategy**.[71]

FDA continued to work with state, local, tribal, and territorial (**SLTT**) public health authorities and responders and public health non-governmental organizations (NGOs) to support MCM preparedness and response capabilities at the state and local levels,

[q] Under PAHPRA, MCMs eligible for RMPs are security countermeasures with respect to which the Secretary of HHS has entered into a procurement contract under section 319F-2(c) of the PHS Act (42 USCS § 247d-6b(c)); or MCMs with respect to which BARDA has provided funding under section 319L of the PHS Act (42 USCS § 247d-7e) for advanced research and development. (FD&C Act Sec. 565(f); 21 U.S.C. § 360bbb-4(f)). While RMPs are to be established for all security countermeasures for which they are requested, the Director of BARDA, in consultation with the FDA Commissioner, prioritizes which otherwise eligible MCMs may receive RMPs if resources are not available to establish RMPs for all eligible MCMs for which requests are submitted. (FD&C Act Sec. 565(f)(7); 21 U.S.C. § 360bbb-4(f))(7))

[r] Guidance documents are documents prepared for FDA staff, applicants/sponsors, industry, and the public that describe FDA's interpretation of or policy on a regulatory issue. Guidance documents include, but are not limited to, documents that relate to: the design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies. (FD&C Act Sec. 565(f)(7); 21 U.S.C. § 360bbb-4(f)(7))

including responding to numerous legal and regulatory inquiries concerning EUA and other emergency use authorities, and MCM stockpiling, expiry dating, distribution, and dispensing. FDA continues to participate in multiple national-level workshops and meetings on public health and legal preparedness. For example, FDA continues to sustain support for and participate in:

- The annual Public Health **Preparedness Summit** convened by the National Association of County and City Health Officials (NACCHO).
- The National Academies of Sciences, Engineering, and Medicine Health and Medicine Division (NASEM-HMD) **Forum on Medical and Public Health Preparedness for Disasters and Emergencies**, to provide national leadership in coordinating ongoing efforts among members from federal, state, and local government; business; and professional associations to develop sustainable partnerships between the public and private sector so that communities are adequately prepared for natural or human-made catastrophic events.
- The Tri-Agency Task Force for Emergency Diagnostics, launched in February 2019, to help leverage the expertise of each agency to better coordinate implementation of diagnostic tests in clinical and public health laboratories during public health emergencies.[72]

Convalescent plasma

Other key collaborations in FY 2020 include:

COVID-19 Convalescent Plasma

Convalescent plasma—the yellow, liquid part of blood that contains antibodies—from patients who have already recovered from COVID-19 may contain antibodies against COVID-19. Giving this convalescent plasma to hospitalized people fighting COVID-19 may lessen the severity or shorten the length of illness caused by COVID-19.

FDA worked closely with the private and public sectors to establish the National Expanded Access Treatment Protocol, an expanded access program that provided access to investigational COVID-19 convalescent plasma for patients that met the criteria of the protocol.[73] FDA also worked with USG and other partners to communicate nationwide the need for volunteers who have recovered from COVID-19 to **donate their plasma**.[74] After an EUA for COVID-19 convalescent plasma was issued on August 23, 2020, the expanded access program discontinued new physician and new patient enrollments, given the much broader access that became available under the EUA. Before the EUA was issued, 85,206 patients were infused with convalescent plasma at 2,747 sites through this program.[75]

FDA also collaborated with NIAID/NIH to design a study of COVID-19 hyperimmune globulin to be conducted by NIAID/NIH, and is part of an NIH-led public-private partnership, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), launched in April 2020 to speed COVID-19 vaccine and treatment options.[76]

DoD

On April 17, 2020, FDA and the U.S. Army Medical Research and Materiel Command **signed an MOU** to establish a training program in the form of an inter-agency detail to support shared interests in the training of scientific and medical personnel in medical product development and FDA's regulatory processes. (See ***Enhanced FDA/DoD Collaborations*** for more.)[77]

NIH and VA

On March 27, 2020, FDA, NIH, and VA **signed an MOU** to share data, and coordinate on open-source medical products for the COVID-19 response with

other stakeholders such as America Makes.[78] (See ***Advanced Manufacturing*** for more.)

NASA

In FY 2018, FDA and the National Aeronautics And Space Administration (NASA) **signed an MOU** to provide mutual support to biomedical research on drugs, biologics, and medical devices and for MCM development.[79] This partnership continues. In April 2020, FDA **authorized a ventilator developed by NASA**, which is tailored to treat patients with COVID-19. The VITAL Compressor ventilator was added to the **list of authorized ventilators, ventilator tubing connectors and ventilator accessories**[80] under the ventilator EUA that was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the COVID-19 pandemic.[81]

CURE Drug Repurposing Collaboratory (CDRC)

In June 2020, FDA initiated a partnership with the Critical Path Institute (C-Path) and the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS) on the **CURE Drug Repurposing Collaboratory** (CDRC).[82] CDRC is a forum for the exchange of clinical practice data to inform potential new uses of existing drugs for areas of high unmet medical need, advancing research in these areas. CDRC will focus on capturing relevant real-world clinical outcome data through the FDA-NCATS CURE ID platform. In a pilot project focused on COVID-19, CDRC will use data collected via the **CURE ID platform** to aggregate global clinician treatment experiences to identify existing drugs that demonstrate possible treatment approaches warranting further study.[83]

International collaborations

In addition to working with federal and SLTT governments and NGOs, FDA continued to work with international partners such as WHO to foster the development and availability of MCMs.

Agreements between FDA and its international counterparts established in previous fiscal years have continued to support information-sharing and collaboration and have better prepared the international regulatory community to respond to COVID-19 and future public health emergencies.

Examples of FDA's key international MCM collaborations include:

- Working with HHS to help establish an international framework for sharing MCMs during an international public health emergency.
- Supporting and participating in the U.S. government's Global Health Security Agenda (GHSA) and strategy,[84] as well as other HHS-led efforts related to global MCM policies, including through Joint External Evaluation (JEE) efforts.[85]
- Implementing CBER-WHO Cooperative Agreements[86] to advance global access to safe and effective vaccines and build capacities for the import, registration, and emergency use of prequalified MCM vaccines.
- Supporting HHS/ASPR's Global Health Security Initiative (GHSI) efforts to strengthen WHO processes for evaluating and making recommendations related to use of MCMs during public health emergencies. The GHSI includes efforts to finalize the WHO operational framework for deployment of smallpox vaccine, and based on this work, establish a generic international framework for sharing MCMs during public health emergencies.
- Participating in international consultations to advance efforts to conduct research, pharmacovigilance, and product development during public health emergencies. For example, FDA is an active participant in:
  - **WHO's R&D Blueprint** - The R&D Blueprint is a global strategy and preparedness plan intended to allow the rapid activation of research and development activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large-scale crisis.
  - **Coalition for Epidemic Preparedness Innovations (CEPI)** - CEPI is an inno-

vative partnership between public, private, philanthropic, and civil organizations that aims to stop future epidemics by developing new vaccines.

- **Global Research Collaboration for Infectious Diseases Preparedness (GloPID-R)** - GloPID-R is the only network of major research funding organizations working on a global scale. Together, these organizations strive to facilitate an effective research response within 48 hours of an infectious disease outbreak.
- **International Coalition of Medicines Regulatory Authorities (ICMRA)** - The ICMRA is comprised of medicines regulators worldwide who have committed to enhanced cooperation with the WHO and among regulatory agencies to encourage submission of regulatory dossiers and evaluation of the submitted information on potential new medicines to address emerging public health threats.
- **Foundation for Innovative New Diagnostics (FIND)** - A WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation, FIND is a global nonprofit organization driving innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations.

Enhancing communication

In addition to extensive COVID-19-related communication, as noted on page 8, in FY 2020, FDA continued ongoing work to enhance communication related to MCM preparedness and response through a variety of outreach activities (e.g., MCMi **email newsletter**, social media,[87] and various presentations).

ENHANCED FDA/DOD COLLABORATIONS

In FY 2018, FDA established a framework for enhanced collaboration with DoD as established under **Public Law 115-92**, which authorized DoD to request, and FDA to provide, assistance to expedite development and FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. In FY 2019, FDA and DoD **signed an MOU** setting forth the framework for the ongoing partnership and the creation of a robust program that can better serve the health care needs of American military personnel.[88, 89] This MOU builds upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.

Utilizing these expanded authorities, FDA is working closely with DoD's Office of Health Affairs to better understand the military's medical needs for deployed personnel; to give the highest level of attention to and to expedite review of priority DoD medical products in a manner similar to products under the

breakthrough therapy designation program; to provide ongoing technical advice to DoD to aid in the rapid development and manufacturing of medical products for use by the military; and to take a closer look at products currently under development to determine opportunities to expedite their availability.[90]

Related to FDA-DoD ongoing and frequent collaborations, in FY 2020, FDA finalized a guidance, **Considerations for the Development of Dried Plasma Products Intended for Transfusion**. Currently approved plasma products intended for transfusion are stored frozen and need to be thawed before being transfused. This significantly limits use in remote areas without freezers and other support equipment, including places where the military may be deployed. Dried plasma products do not need to be stored frozen and can be reconstituted and administered quickly. By developing guidance on this topic, FDA hopes to expedite the development and approval of safe and effective dried plasma products.[91]

Blood plasma

MEDICAL COUNTERMEASURE REGULATORY SCIENCE

In FY 2020, FDA continued to implement the **MCMi Regulatory Science Program** through both intra- and extramural collaborative research, as well as through partnerships with U.S. government agencies, academia, and industry.[s]

MCMs often present unique and complex challenges with respect to developing the data necessary to support public health, clinical, and regulatory decision-making. For example, many of the high-priority threats for which MCMs are being developed do not occur naturally to an extent that would support the conduct of field efficacy studies in humans, and it is not ethical to conduct human challenge studies with threat agents that would pose unacceptable risks to study volunteers. In these situations, efficacy data from animal studies may be used if the results can reasonably be extrapolated to expected human use.

The challenges are even more complex when it comes to developing MCMs for use in specific populations, such as children or pregnant women. For example, ethical evaluation of the participation of children in clinical trials depends on both the level of risk and the prospect of direct benefit to the participant. Thus, in some circumstances it may not be ethical to conduct certain types of clinical trials in the pediatric population to obtain data that can be used for approving pediatric indications for MCMs—such as safety or dosing information—and FDA may rely on the extrapolation of efficacy data from adult populations, along with information and experience the agency has with the use of a particular class of product (e.g., monoclonal antibodies for use in the pediatric population) to the extent permitted by law.[92]

The goal of the MCMi Regulatory Science Program is to develop tools, standards, and approaches to assess MCM safety, efficacy, quality, and performance,

[s] Many projects described in this section are preliminary and/or exploratory in nature. Listing a project does not imply any determination with regard to utility in public health, clinical, or regulatory decision-making.

and to help translate cutting-edge science and technology into innovative, safe, and effective MCMs, including for specific populations.

FDA has established a broad and robust intra- and extramural research portfolio under the MCMi Regulatory Science Program to meet its goals in these priority research areas.[93] To ensure that the MCMi Regulatory Science Program is appropriately targeted and coordinated with USG MCM priorities, FDA coordinates with interagency partners including representatives from NIH, CDC, BARDA, and DoD to evaluate MCMi Regulatory Science Program research proposals for scientific/technical merit, feasibility, and for alignment with PHEMCE priorities. FDA continually engages with USG stakeholders to maintain an MCMi Regulatory Science Program that actively addresses current regulatory science gaps.

> The MCMi Regulatory Science Program helps translate cutting-edge technologies into innovative, safe, and effective MCMs

MCM-related **regulatory science research tools** funded (or partially funded) by FDA are available at no charge to help MCM researchers advance their products, and help FDA reviewers evaluate MCM products for approval.[94]

Since late January 2020, FDA has initiated a number of regulatory science projects to support development and evaluation of MCMs that would prevent, treat, or diagnose COVID-19. Some notable activities since these efforts began include:

- Developing a reference panel to aid in the evaluation of diagnostic tests for SARS-CoV-2. The reference panel provides test developers with well characterized reagents to compare the sensitivity and specificity of different molecular diagnostic tests.[95]
- Participating in evaluation of antibody and RNA reference materials that are being developed by the National Institute of Biological Standards and Control under the auspices of the WHO, as candidate international standards for assays used for SARS-CoV-2/COVID-19.
- Evaluating small and large animal models for studying immune responses to COVID-19 vaccines.
- Developing assays that support evaluation of vaccine immune responses.

In an important example of how regulatory science research translates to increased availability of MCMs, an MCMi-funded **pilot study** completed in 2016 provided the data needed for EUA of the Battelle CCDS Critical Decontamination System for use in decontaminating compatible N95 respirators during the COVID-19 public health emergency. This EUA, initially issued in March 2020,[96] was an important step forward in helping to reduce shortages in critical N95 respirators by authorizing these important devices, when decontaminated, to be reused by medical professionals on the front lines of the COVID-19 pandemic.[97]

In FY 2020, FDA posted to our website a **catalog of regulatory science tools to help assess new medical devices**. This catalog collates a variety of regulatory science tools that the FDA's CDRH Office of Science and Engineering Labs (OSEL) developed and plans to expand as new tools become available. FDA also updated its **Regulatory Science Research Tools** web page with additional information about regulatory science tools funded, at least in part, by FDA, and freely available to researchers, including the FDA SARS-CoV-2 reference panel.[98] Funded by MCMi, the FDA SARS-CoV-2 Reference Panel allows for a more precise comparison of the analytical performance of different molecular IVD assays intended to detect SARS-CoV-2. The Reference Panel contains common, independent, and well-characterized reference material that is available to developers of SARS-CoV-2 nucleic acid-based amplification tests (NAATs) for which EUA was requested. FDA has made **SARS-CoV-2 Reference Panel comparative data** publicly available.[99]

FDA also continued work to build and maintain a national capability to **monitor and assess MCMs** after they are dispensed or administered in response to a CBRN threat or emerging infectious disease.

In FY 2020, FDA continued collaboration with Harvard Pilgrim Health Care to explore how the Sentinel System—an active surveillance system that uses routine querying tools and pre-existing electronic health care data from multiple sources to monitor the safety of regulated medical products—may inform study protocols for MCM safety and effectiveness and to provide a valuable baseline for comparison during a public health emergency. The FDA Sentinel System is conducting a number of **activities in support of the COVID-19 response**.[100] Additionally, FDA is participating in the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (**SHIELD**) **collaborative**,[101] in partnership with the COVID-19 **Diagnostics Evidence Accelerator**,[102] to harmonize COVID-19 test data referenced in the HHS COVID-19 laboratory data reporting requirements,[t] to support evaluation of real-world performance of SARS-CoV-2 diagnostic tests and antibody tests.

FY 2020 MCMi Regulatory Science program activities are included in ***Table 7***.

[t] COVID-19 Pandemic Response, Laboratory Data Reporting: Coronavirus Aid, Relief, and Economic Security (CARES) Act Section 18115, available at: **https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf**

Table 7: MCMi Regulatory Science Program activities in FY 2020
CBRN
Developing models of radiation damage in lung, gut, and bone marrow **organs-on-chips** and then using these models to test candidate MCMs to treat such damage. In FY 2020, the project began analyzing the interplay between human bone marrow organs-on-chips and intestine organs-on-chips that include a complex human gut microbiome in response to radiation exposure.
Exploring nanopore technology to enhance detection and tracing of *Clostridium botulinum* and *Escherichia coli* contamination
Providing recommendations for radiation biodosimetry device pre-EUA submissions
Conducting exploratory analysis of 3D printing of biologics to support development of MCMs for burn/blast and radiation-induced injuries
Developing immunoassays for rapid and sensitive detection of ricin, botulinum, and abrin toxins in novel formats
Emerging threats (e.g., SARS-CoV-2, Ebola, and Zika)
Expanding a **database of reference-grade nucleic acid sequences** for emerging threats, to include viruses such as Ebola and Zika, and antimicrobial-resistant pathogens. In April 2020, **SARS-CoV-2 reference-grade sequence data** was added to the FDA-ARGOS database[103]
Distributed **Zika virus RNA reference materials** to manufacturers of nucleic acid-based diagnostic tests for Zika virus, which **supported product testing for EUA and 510(k) submissions**[104]
Distributed **Zika serological reference panel** to manufacturers seeking EUA for serological diagnostic tests specific for detection of recent Zika virus infection
Providing Zika test developers with study recommendations for Zika nucleic acid-based diagnostic tests and Zika serological assay premarket submissions
Continuing to support improvement of small and large animal models for emerging threats (e.g. SARS-CoV-2, Ebola, and Zika)
Conducting survivor studies to better understand Ebola's after-effects, to help find new treatments. In March 2020, FDA awarded a contract modification to support development and evaluation of potential MCMs for COVID-19.
Identifying target peptide sequences for a Zika IgM diagnostic device
Exploring antibody responses following Zika virus infection or vaccination in humans, to help support development of effective vaccines and serodiagnostics
Developing microphysiological systems (MPS) models for emerging threats (including Zika and SARS-CoV-2) as tools to support MCM development
Applying advanced transcriptomic analysis (the study of all messenger RNA from the genes of an organism) to **compare responses to Ebola virus disease in humans and in animals**, to help identify biomarkers of Ebola, and expected disease outcomes. In FY 2020 this project was modified to complete multiple short-term research objectives for COVID-19, including sequencing and development of COVID-19 pseudovirus, development of COVID-19 reagents for regulatory science, and exploration of animal models for MCM development.
Studying **antibody responses** in Ebola survivors and in vaccinated individuals, and evaluation of potential countermeasures
In collaboration with DoD, working to better understand the **microbial pathogenesis** of Ebola, Marburg, Rift Valley fever, Crimean Congo hemorrhagic fever, Chikungunya, and Zika viruses
Conducting the largest Ebola virus and host gene expression (i.e., transcriptomics) study to date, using the latest sequencing technologies, including single-cell sequencing methods, to **assess how Ebola virus evolves and spreads** within the body

Developing a **unique biobank** of clinical Ebola samples from over 2,500 participants, including investigational Ebola vaccines and Ebola survivors, to characterize the durability and correlates of vaccine-induced and natural immunity to EVD
Analyzing SARS-CoV-2, SARS-CoV, and MERS-CoV clinical samples, collected through global partnerships, to better understand coronavirus evolution and virulence, characterize host-pathogen interactions and immunity, and identify biomarkers of disease progression and severity[105]
Profiling circulating immune signatures of coronavirus infection and completing COVID-19 pathology tissue imaging, leveraging novel tools to define the characteristics of tissue viral reservoirs (cell types or areas of the body where the virus persists), and learning more how SARS-CoV-2 affects different systems in the body[106]
Developing and distributing a **reference panel to aid in the evaluation of diagnostic tests for SARS-CoV-2**. The reference panel provides test developers with well characterized reagents to compare the sensitivity and specificity of different molecular diagnostic tests.[107]
Participating in evaluation of antibody and RNA reference materials that are being developed by the National Institute of Biological Standards and Control under the auspices of the WHO, as candidate international standards for assays used for SARS-CoV-2/COVID-19
Developing assays that support evaluation of vaccine immune responses
Collaborating with NIH to design a study of hyperimmune globulin to be conducted by NIAID/NIH
Developing models of emerging infectious diseases (such as Ebola, Zika, and SARS-CoV-2) in organ chips for potential testing of MCMs
Pandemic influenza
Demonstrating the ability of a universal influenza vaccine candidate to **reduce the transmission of influenza virus** in mice, even though this vaccine does not completely block infection by the virus[108]
Developed **two candidate vaccine viruses** that may be used as the starting material for production of inactivated influenza vaccines[109]
Characterizing immune responses against influenza virus proteins to support development of pandemic and universal influenza vaccine
Evaluating the impact of influenza polymerase mutations on influenza replication and sensitivity to anti-influenza drugs
Public health emergency preparedness and response
Exploring how the Sentinel System may **inform study protocols** for MCM safety and effectiveness, and provide a baseline for comparison during a public health emergency. In FY 2020, the project successfully completed a study to collect and analyze MCM data for influenza patients. The project was expanded in March 2020 to incorporate and analyze COVID-19 patient cohorts.
Continuing support of the **CDC & FDA Antibiotic Resistance (AR) Isolate Bank**

FDA also expanded and sustained MCM regulatory science collaborations in FY 2020. For example, FDA:

- Continued collaborations with the Defense Advanced Research Projects Agency (DARPA) and Defense Threat Reduction Agency (DTRA) on regulatory science research for the development of innovative regulatory tools, such as biomimetic models.
- Continued work with the interagency National Interagency Confederation for Biological Research (NICBR) to collaborate and share technical expertise and scientific services in the pursuit of a healthier and more secure nation.
- Continued to support a three-year interagency agreement with USAMRIID to **establish a better understanding of the microbial pathogenesis of several viruses**: Ebola, Marburg, Rift Valley fever, Crimean Congo hemorrhagic fever, Chikungunya virus, and Zika. This project leverages the U.S. Army's Joint Mobile Emerging Disease Intervention Clinical Capability (JMEDICC) project.
- Continued collaborations with NIAID to support innovative analytical technologies for emerging infectious diseases through co-sponsorship of Stanford University's **Survivor Studies: Better Understanding Ebola's After-Effects to Help Find New Treatments** and University of Liverpool's **FDA and Global Partners to Analyze Coronavirus Samples** projects.
- Continued collaborations with the **Bill and Melinda Gates Foundation** on the development and evaluation of home-use influenza diagnostic tests and other common goals to improve public health by stimulating and fostering medical product innovation and enabling medical product development, including MCMs.
- Continued collaborations with NASA on regulatory science research to develop and provide MCMs to support human space exploration.
- Continued serving as one of 14 voting representatives on the HHS Tick-Borne Disease Working Group, established under Section 2062 of the Cures Act [PL 114-255]. The working group is developing recommendations on how to address the growing incidences of diseases transmitted by ticks.[110]
- Continued collaborating and meeting with CDC, BARDA, NIH, DoD, USDA, the Environmental Protection Agency (EPA), the U.S. Geological Survey (USGS), and DHS to help develop a national strategy on vector-borne diseases to develop a comprehensive national system to detect, prevent, and respond to these threats. This is a sustained effort to address significant challenges and reverse the upward trends in illness, suffering, and death from vector-borne diseases.

FDA also continues to create and support programs to advance the development and review of MCMs that will be regulated under the **Animal Rule**.[u] For example, in FY 2020 FDA:

[u] Before a medical product can be approved by FDA, the sponsor must prove the product's safety and its efficacy. FDA has regulations commonly known as the Animal Rule that allow, under very limited circumstances, FDA to grant approval of a drug or biological product based of effectiveness demonstrated in adequate and well-controlled efficacy studies in animal models of the human disease or condition of interest, when the results of those studies establish that the product is reasonably likely to produce clinical benefit in humans. The product sponsor must still demonstrate the product's safety in humans. The Animal Rule can be used only for drug and biological products that are intended to prevent or reduce serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological, or nuclear substances when (1) it has not been feasible to study the product's effectiveness definitively in natural, accidental, or hostile occurrences of the disease or condition and (2) it would not be ethical to induce the disease or condition in human volunteers for study purposes, and if a proposed countermeasure cannot be approved through other existing regulatory pathways. Also see Animal Rule Information at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/animal-rule-information**

- Announced the beginning dates for FDA's support of and the requirement to use the Clinical Data Interchange Standards Consortium (**CDISC**) for Study Data Tabulation Model version 1.8 (SDTM v1.8) and CDISC Standard for Exchange of Nonclinical Data Implementation Guide – Animal Rule version 1.0 (**SENDIG–AR v1.0**). FDA's support of these new electronic data standards began on March 15, 2020.
- Continued to support the **Animal Model Qualification Program**, which provides a mechanism for the evaluation of product-independent animal models for use in drug and biological product development under the Animal Rule.

ADVANCED MANUFACTURING

Advanced manufacturing can accelerate therapy development, rapidly scale manufacturing capabilities for vaccines and other MCMs, as well as shorten supply chains to increase manufacturing resilience. The potential public health value of advanced manufacturing is even greater in the context of the ongoing COVID-19 pandemic, which has highlighted the strain on supply chains and the need for adaptive manufacturing systems to accelerate the production of MCMs. The FDA has established a strong regulatory foundation to support the uptake of advanced manufacturing, and COVID-19 provides the unique impetus to spur further advancement of medical manufacturing.[111]

> Advanced manufacturing is a collective term for new medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market

In March 2020, FDA **entered an MOU** with the VA Innovation Ecosystem and the NIH 3D Print Exchange to share data, and coordinate on open-source medical products for the COVID-19 response. These agencies are also working closely with America Makes, to provide resources that connect health care providers and 3D printing organizations. Through this partnership, 3D-printable designs for COVID-19 response are given a clinical assessment by the VA, and the NIH posts them on the 3D Print Exchange. FDA has, among other things, provided information on labeling and testing for face shields and face masks. In

the program's first three months, 31 community-submitted designs passed the testing performed by VA clinics and were given clinically reviewed status. As of June 2020, this effort has matched more than 500,000 3D-printed face shields and more than 348,000 3D-printed face masks with health care providers and others in need.[112] In May 2020, FDA hosted a **virtual town hall on 3D-printed swabs**, to discuss the production and use of 3D printed swabs during the COVID-19 public health emergency.[113]

Prior to COVID-19, the FDA and the U.S. Army Medical Logistics Command conducted a meeting on additive manufacturing of medical devices and medical device components. FDA shared regulatory considerations and updates on additive manufacturing with the U.S. Army and other branches of the military. The groups agreed to have continued discussions on additive manufacturing of medical devices in the future.

In September 2019, FDA awarded an extramural research contract to conduct a landscape assessment of the adoption of advanced manufacturing and identify barriers to adoption within the medical device industry. In September 2020, FDA awarded an extramural research contract to identify barriers to implementing advanced manufacturing in critical production areas such as vaccines and biopharmaceuticals. Such technologies and processes may increase the domestic production of critical MCMs and other medical products needed for pandemic or other response activities.

In FY 2019, FDA signed a Cooperative Research and Development Agreement (CRADA) with the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). NIIMBL is a

> An FDA collaboration with NIH and VA matched 500,000+ 3D-printed face shields and 348,000+ 3D-printed face masks with health care providers and others in need during the COVID-19 pandemic

An FDA researcher completes a 3D print of several clinical and research tools for patient-specific medicine.

Manufacturing USA public private partnership (PPP) dedicated to advancing biopharmaceutical manufacturing innovation and workforce development. The CRADA allows FDA to collaborate with biotech stakeholder NIIMBL members, accelerating Agency and industry adoption of biotech innovations. FDA actively engages with other PPPs, many of which are **Manufacturing USA Institutes**, including **America Makes**, **BioFabUSA**, and **NextFlex**, to proactively address regulatory challenges presented by advanced manufacturing technologies, including continuous manufacturing. In addition to PPPs, FDA is engaging with industry and government consortia, such as the **4D Bio**[3] consortium of the Uniformed Services University, Naval Research Laboratory, and Walter Reed National Military Medical Center, dedicated to bringing advanced technologies and therapies to military personnel. This work continues and is bolstered by changing needs.

Since 2015, FDA has been working with BARDA to advance innovations in manufacturing for

BARDA-supported MCMs, including those manufactured in HHS Centers for Innovation in Advanced Development and Manufacturing (**HHS-CIADM**) facilities. In addition, FDA coordinated with DoD on the opening of its DoD Medical Countermeasures Advanced Development and Manufacturing (MCM ADM) facility, and continues to support ongoing operations. These innovations in manufacturing technology will help enable rapid ramp-up of manufacturing capabilities for vaccines and other MCMs to respond to emerging threats and other public health emergencies, such as pandemic influenza. These technologies could also accelerate the development of therapies for orphan diseases by improving the cost-efficiency of small-scale manufacturing processes, and enable manufacturing process and standards development for emerging therapies including cell and gene therapies, supporting goals of the Cures Act.

In December 2017, FDA became the first regulator worldwide to provide a comprehensive technical framework to advise manufacturers creating medical products on 3D printers, by issuing the guidance **Technical Considerations for Additive Manufactured Medical Devices**. To date, FDA has cleared more than 150 3D-printed medical devices and has approved a **3D-printed drug**. Since releasing this guidance, FDA has worked closely with America Makes on a Standards Roadmap for 3D printing. FDA's continued interaction with stakeholder groups, including the Department of Veterans Affairs Innovation Network is facilitating advanced 3D-printed solutions that are reaching civilian and military patients.

This 3-D printed prosthetic hand was printed and assembled by FDA researchers in their CDRH laboratory.

To support innovation in this field, FDA has led the world in advancing efforts to provide a comprehensive regulatory framework to manufacturers and a more effective pathway to getting state-of-the-art medical products into the hands of patients and health care providers. Examples include CDER's **Emerging Technology Program**, which provides opportunities for early engagement regarding innovative approaches to pharmaceutical product design or manufacturing.

Under this program, FDA has approved 11 applications involving advanced manufacturing, including 10 that used continuous manufacturing. For example, during the COVID-19 pandemic, FDA approved two supplemental applications that used advanced manufacturing in a U.S. facility to address the potential shortage of two critical drug products. The new **CBER Advanced Technology Team** was also started to promote communication between CBER and prospective innovators/developers of advanced manufacturing technologies.

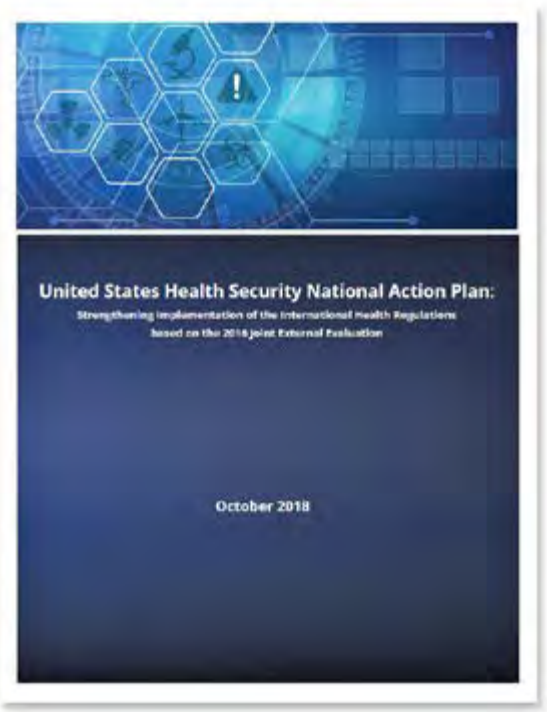
MEDICAL COUNTERMEASURE REGULATORY POLICY

During FY 2020, FDA continued efforts to ensure that the FDA **legal, regulatory and policy framework** enables the application of advances in regulatory science to the regulatory review process and adequately supports preparedness for and response to CBRN and emerging infectious disease threats by facilitating the development and availability of MCMs. In addition to addressing policy aspects of those activities described generally throughout this document (see ***Box 1***, and ***COVID-19 Response***), examples of FDA advancing policy-specific efforts in FY 2020, as discussed in more detail in other sections, include:

- Advancing efforts to create a national capability to track, collect, analyze, and evaluate information related to MCMs used during public health emergencies to inform real-time decisions about the safety and effectiveness of these MCMs.
- Addressing issues related to use of expanded access mechanisms and EUAs to make available unapproved MCMs for CBRN and other emerging infectious disease threats and for certain DoD-related threat agents.
- Supporting an adequate supply of MCMs through efforts to extend the shelf life of certain MCMs outside of SLEP, utilizing authorities under section 564A(b) of the FD&C Act.
- Leading or providing policy subject matter input to FDA MCM-related collaborations, including with DoD under PL 115-92.
- Maintaining a surveillance program that routinely monitors online sources for fraudulent products, especially during public health emergencies, such as COVID-19 and Ebola.
- Updating regulatory policy to improve availability of blood and blood components, ensure adequate protections for donor health and maintain a safe blood supply for patients.
- Clarifying regulatory issues around building frameworks for conducting clinical trials during public health emergencies.
- Participating in interagency emergency preparedness exercises and follow up activities, including the HHS Crimson Contagion Exercise Series, which focused on a pandemic involving a novel strain of influenza, and the DHS/FEMA Shaken Fury Exercise,[114] which involved issues related to foreign medical teams and the import of foreign medical products for a domestic response.
- Working to prepare a **list of essential medicines, MCMs, and critical inputs** required by an Executive Order issued on August 6, 2020.[115] The goal of the executive order is to ensure that the U.S. is able to protect patients and our military forces against emerging infectious diseases, such as COVID-19 as well as CBRN threats. To accomplish this goal, the executive order seeks to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing our dependence on foreign manufacturers of these products.[116]
- During the COVID-19 pandemic, Section 506J of the FD&C Act (21 U.S.C. 356j) was added giving the FDA certain authorities related to device shortages and potential device shortages occurring during a public health emergency. This authority requires manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the U.S. This provides the FDA with better visibility of the medical devices supply chain. FDA issued an immediately in effect guidance document, **Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency**, to implement section 506J of the FD&C Act.

FDA also continued to develop and propose new approaches for addressing legal, regulatory, and policy challenges associated with the development and use of MCMs. For example, FDA is:

- Continuing work to harmonize the multi-jurisdictional regulation of certain PPE that may be used during public health emergencies, such as COVID-19 and pandemic influenza.
- Continuing to address issues related to information disclosure, including related to COVID-19 interagency activities, and liability protections related to MCM products.
- Identifying and developing new legislative proposals, providing technical assistance on others' legislative proposals, supporting MCM-related congressional testimony, and providing technical support for passage and implementation of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) (**PL 116-22**), which reauthorizes and modifies programs related to public health emergency preparedness and response[117] and the CARES Act (PL 116-136).
- Leading development of or providing policy input to MCM-related guidance documents issued in FY 2020 (***Appendix 3: MCM-Related Guidance Issued in FY 2020***), key meetings and workshops (***Appendix 4: Key MCM-Related Meetings Held in FY 2020***), and information for stakeholders about key MCM-related authorities.
- Working with CDC and CMS to leverage the expertise of each agency to collaborate on and address issues related to the implementation of EUA diagnostic tests in clinical and public health laboratories during public health emergencies.
- Supporting development of the **U.S. Health Security National Action Plan: Strengthening Implementation of the International Health Regulations** based on the 2016 JEE, containing hundreds of cross-sectoral activities to better prepare the U.S. to prevent, detect, and respond to public health emergencies. HHS/ASPR led the coordination of the plan's development, working closely with the National Security Council (NSC) and more than 40 U.S. government departments and agencies, including FDA, to identify key activities and ensure long-term support for its implementation.



- Drafted **MOUs** to provide frameworks for FDA collaborations.

During FY 2020, FDA continued working to implement several additional MCM-related provisions of the **Cures Act**, which was signed into law in December 2016. Specifically, the Cures Act amended the FD&C Act to allow FDA to establish a new priority review voucher (PRV) program for material threat MCMs. FDA developed a **draft guidance**[118] that provides to internal and external stakeholders answers to questions FDA has received on material threat **MCM PRVs**. FDA issued this draft guidance in January 2018, to explain to internal and external stakeholders how FDA intends to implement the material threat MCM PRV program. On September 25, 2019, FDA issued a notice establishing the FY 2020 user fees for MCM PRVs.[119] FDA had issued two material threat MCM PRVs as of the end of FY 2020.[120]

The Cures Act also amended the FD&C Act to permit Institutional Review Board (IRB) waivers of informed consent for minimal risk studies.[v] In November 2018, FDA **proposed to amend** its regulations to implement these provisions and add an exception to informed consent requirements for certain FDA-regulated clinical investigations that present no more than minimal risk to human research participants.[121]

In addition, throughout FY 2020, FDA continued work to implement Public Law 115-92, enacted in December 2017, which amended FDA's EUA authorities to allow for emergency uses of medical products for threats in addition to CBRN agents, to include other agents that may cause or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces.

FDA also continues to work with DoD to implement Public Law 115-92's provisions for enhanced engagements to expedite development and FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel.

PROFESSIONAL DEVELOPMENT

FDA launched the **MCMi Professional Development Program** during FY 2011 to ensure that FDA scientists are informed about CBRN threats and associated health impacts as they conduct benefit-risk analyses on MCMs, and that FDA scientists can meet the regulatory challenges posed by new areas of science and technology in the area of MCM development.

[v] Minimal risk research is research in which the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. See 45 Code of Federal Regulations (CFR) 46.303(d).

In FY 2020, FDA continued efforts to launch a new program designed to train recent pre- and post-doctoral scientists and physicians in research disciplines relevant to FDA's mission. Although the traineeship program is not limited to traineeships involving MCMs, it advances MCMi Program goals to improve and advance MCM science and train reviewers in MCM review processes.

Due to the COVID-19 pandemic, the MCMi professional development program held fewer training sessions than in previous years. Activities in FY 2020 included:

MCMi Intramural Research and Collaborative Lecture Series

This lecture series, initiated in FY 2019, brings together the FDA research community to engage with FDA scientists supported by the MCMi Intramural Regulatory Science Program to share ideas and knowledge, and inspire continued advancement in MCM regulatory science. These sessions are designed for an FDA audience, including scientists involved in the review of medical product applications. FDA held four lectures in this series during FY 2020 with a total 146 attendees.

Data quality and integrity training for high-consequence pathogens

FDA also sponsored the eighth installment of a **week-long training course** with the University of Texas Medical Branch (UTMB) to provide training on best practices to ensure the quality and integrity of data generated in maximum-containment (i.e., biosafety level (BSL)-3 and -4) laboratories used to support product approval under the Animal Rule, which was to occur April 20-24, 2020, but has been postponed following planning and course redesign in response to the ongoing COVID-19 pandemic.

Continuing on the success of a 2019 pilot clinical course, FDA/UTMB successfully launched the full clinical course, **Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens** on October 26 – 28, 2020. This course is designed to provide a learning environment that cultivates collaboration of ideas; yields tools for clinical study conduct; enhances mutual understanding of clinical, scientific, and regulatory complexities; and promotes the data quality and integrity derived from these regulated studies according to Good Clinical Practice (GCP) principles.[w]

To date, 537 individuals have attended these courses.

[w] Though planned for one week, including a full-day hands on clinical practicum, the COVID-19 pandemic limited the 2020 clinical course to three days of virtual lectures, including two separate expert panel discussions, which were held October 26-28, 2020 (FY 2021).

APPENDIX 1: FY 2020 MEDICAL COUNTERMEASURE APPROVALS – BIOLOGICS AND DRUGS[x,y]

Medical Countermeasure	Applicant	Key Dates	Indication
AUDENZ (Influenza A (H5N1) Monovalent Vaccine, Adjuvanted)	Seqirus Inc.	• Submitted January 31, 2019 • Approved January 31, 2020	For active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. AUDENZ is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.
ERVEBO (Ebola Zaire Vaccine, Live)	Merck Sharp & Dohme Corp.	• Submitted July 12, 2019 • Approved December 19, 2019	For the prevention of EVD, caused by *Zaire ebolavirus* in individuals 18 years of age and older. This is the **first FDA-approved vaccine** for the prevention of EVD.
Fluzone High-Dose Quadrivalent	Sanofi Pasteur Inc.	• Submitted October 4, 2019 • Approved November 4, 2019	Supplemental BLA for high-dose quadrivalent (four-strain) flu vaccine for use in those age 65 and older.
Xofluza (baloxavir marboxil)	Genentech, Inc.	• Submitted January 4, 2019 • Approved October 16, 2019	Supplemental NDA for the treatment of acute, uncomplicated influenza in people 12 years of age and older who have been symptomatic for no more than 48 hours and who are at high risk of developing flu-related complications.

[x] Includes MCMs approved, licensed, or cleared by FDA in FY 2020 (October 1, 2019 - September 30, 2020).

[y] For products (biologics) regulated by CBER, additional information can be found at: **https://www.fda.gov/vaccines-blood-biologics/biologics-products-establishments**; for products (drugs and biologics) regulated by CDER, additional information can be found at: **http://www.accessdata.fda.gov/scripts/cder/daf/**. The Purple Book Database of Licensed Biological Products is available at: **https://purplebooksearch.fda.gov/**

APPENDIX 2: FY 2020 MEDICAL COUNTERMEASURE APPROVALS – DEVICES[z,aa]

Medical Countermeasure	Applicant	Key Dates	Indication
Diagnostic Tests			
***Bacillus anthracis* Detection Kit**	MDC Associates, LLC	• Received December 14, 2019 • Cleared October 1, 2019	Real-time PCR test kit intended for the qualitative IVD detection of target DNA sequences for *B. anthracis*, the bacteria that causes anthrax.
BioCode Respiratory Pathogen Panel (RPP)	Applied BioCode, Inc.	• Submitted September 10, 2019 • Cleared December 23, 2019	A qualitative multiplexed nucleic acid-based IVD test intended for use with BioCode MDx-3000 Instrument. The BioCode RPP is capable of the simultaneous detection and identification of nucleic acids from multiple viruses and bacteria extracted from nasopharyngeal swab (NPS) samples obtained from individuals with signs and/or symptoms of respiratory tract infection. Pathogens detected include *Bordetella pertussis*, *Chlamydia pneumoniae*, influenza A and subtypes H1, H3 and H1N1 2009pdm, influenza B, and other common viruses and bacteria in nasopharyngeal swabs.
DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader	Chembio Diagnostics, Inc.	• Submitted March 2, 2020 • Cleared June 3, 2020	For the presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood specimens, collected from individuals meeting the CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

[z] Includes MCMs approved, licensed, or cleared by FDA in FY 2020 (October 1, 2019 - September 30, 2020).

[aa] Additional information about device approvals can be found in Medical Devices Databases: **https://www.fda.gov/medical-de- vices/device-advice-comprehensive-regulatory-assistance/medical-device-databases**, including the 510(k) Premarket Notification Database: **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm**

Medical Countermeasure	Applicant	Key Dates	Indication
LIAISON XL Zika Capture IgM Assay II and LIAISON XL Zika Capture IgM II control set	DiaSorin Inc.	• Received July 31, 2019 • Cleared October 28, 2019	For the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting the CDC Zika virus clinical and/or epidemiological criteria.
OraQuick Ebola Rapid Antigen Test	OraSure Technologies, Inc.	• Received May 13, 2019 • Cleared October 10, 2019	To detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola (cadaveric oral fluid). The OraQuick Ebola Rapid Antigen Test is the **first rapid diagnostic test** the FDA has allowed to be marketed in the U.S. for EVD. The test provides a rapid, presumptive diagnosis that must be confirmed.
Personal Protective Equipment (PPE)			
50g SMS Standard Surgical Gown, 45g SMS Surgical Gown with Reinforcement, 68g BVB Surgical Gown, 68g BVB Splicing Surgical Gown	Xuchang Zhengde Environstar Medical Products Co., Ltd	• Received August 23, 2019 • Cleared April 30, 2020	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, SMS Standard Surgical Gown and SMS Surgical Gown with Reinforcement met the requirements for Level 3 classification; BVB Surgical Gown and BVB Splicing Surgical Gown met the requirements for Level 4 classification.
Biodegradable Nitrile Examination Powder Free Glove, Green	Top Glove SDN BHD	• Received August 5, 2020 • Cleared September 3, 2020	The Biodegradable Nitrile Examination Powder Free Glove, Green is a non-sterile disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	Hartalega NGC SDN BHD	• Received March 5, 2020 • Cleared April 25, 2020	Biodegradable Nitrite Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate,

Medical Countermeasure	Applicant	Key Dates	Indication
Biogel Skinsense Indicator Underglove, Biogel PI Ultratouch, Biogel PI Indicator Underglove, Biogel PI, Biogel PI Micro	Molnlycke Health Care US LLC	• Received December 23, 2019 • Cleared April 10, 2020	A powder-free, sterile, surgeon's glove is a disposable device made of non-latex that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. **Please see the 510(k) summary for the full indications for use**.
Black Colored Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Comfort Rubber Gloves Industries Sdn. Bhd	• Received January 24, 2020 • Cleared April 15, 2020	The Black Colored, Power Free Nitrite Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested for use chemotherapy drugs and Fentanyl Citrate.
Cardinal Health SMARTGOWN Breathable Surgical Gown, Cardinal Health SMARTGOWN AIR Breathable Surgical Gown	Cardinal Health 200, LLC	• Received March 30, 2020 • Cleared July 29, 2020	Cardinal Health SMARTGOWN Breathable Surgical Gown and Cardinal Health SMARTGOWN AIR Breathable Surgical Gown are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The gowns meet the barrier protection requirements of Association for the Advancement of Medical Instrumentation (AAMI) Level 4 per AAMI PB70:2012 Liquid Barrier and Performance. Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities. The Cardinal Health SMARTGOWN Breathable Surgical Gown and Cardinal Health SMARTGOWN AIR Breathable Surgical Gown are single use, disposable medical devices provided sterile and non-sterile.
ClearMask Transparent Surgical Face Mask	ClearMask, LLC	• Received March 5, 2020 • Cleared April 6, 2020	The ClearMask Transparent Surgical Face Mask is intended for use in health care settings, such as in operating rooms, or in other medical procedures such as dental, isolation and veterinary procedures during which a face mask is necessary to protect both patient and health care personnel from transfer of body fluids, microorganisms, and particulate material. The device allows for full view of the face and facial expressions, particularly the nose and mouth areas. The device is indicated for over-the-counter use. The device is disposable and is indicated for single use. The device is not provided sterile.

Medical Countermeasure	Applicant	Key Dates	Indication
DemeMASK	DemeTECH Corporation	• Received June 4, 2020 • Cleared July 24, 2020	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and health care personnel from transfer of micro-organisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.
Disposable Medical Face Mask	JKH USA, LLC	• Received June 3, 2020 • Cleared September 8, 2020	The Disposable Medical Face Masks are intended to be worn to protect both the patient and health care personnel from transfer of micro-organisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate	Ever Global (Vietnam) Enterprise Corp	• Received December 20, 2019 • Cleared June 4, 2020	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with American Society for Testing and Materials (ASTM) D6978-05 standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs.
Disposable Surgical Mask	Unisources Group LLC	• Received August 27, 2020 • Cleared September 18, 2020	The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of micro-organisms, body fluids and particulate material. The disposable surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Disposable Vinyl Glove	Best Care Trading Co., LTD	• Received July 21, 2020 • Cleared September 10, 2020	The Disposable Vinyl Glove is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

Medical Countermeasure	Applicant	Key Dates	Indication
F&P Evora Nasal Mask Nasal A Model, F&P Evora Nasal Mask Nasal Fit Pack/ SML A Model, F&P Evora Nasal Mask Nasal Sleep Lab, F&P Evora Nasal Mask Nasal Fit Pack / SML Sleep Lab Model	Fisher & Paykel Healthcare Ltd.	• Received January 15, 2020 • Cleared June 2, 2020	**The A Model:** The F&P Evora Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed noninvasive positive airway pressure therapy such as CPAP or bilevel by a physician. The F&P Evora Nasal Mask is intended for single patient use in the home. **SL Model:** The F&P Evora Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed noninvasive positive airway pressure therapy such as continuous positive airway pressure (CPAP) or bilevel by a physician. The F&P Evora Nasal Mask is intended for single patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.
Halyard Pink Underguard Zero, Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs	O&M Halyard, Inc.	• Received March 31, 2020 • Cleared September 22, 2020	The Halyard Pink Underguard Zero Nitrile Sterile Powder-Free Exam Gloves Tested with Chemotherapy Drugs are disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
KIMTECH Purple Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs, the Opioid Fentanyl, Gastric acid, and Fentanyl in Gastric acid	Kimberly-Clark Corporation	• Received January 14, 2020 • Cleared April 10, 2020	The Nitrile Powder Free patient examination glove is non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Latex Examination Powder Free Glove, Aloe Vera	Top Glove SDN BHD	• Received November 13, 2019 • Cleared June 5, 2020	A patient examination glove is disposable glove intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
MCare Powder Free Nitrile Orange Examination Gloves	Mercator Medical (Thailand) LTD.	• Received April 10, 2020 • Cleared June 6, 2020	mCare Powder Free Nitrile Orange Examination Gloves are disposable device intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.
Medline Powder Free Examination Gloves (Tested for use with Chemotherapy Drugs)	Medline Industries, Inc.	• Received April 10, 2020 • Cleared July 13, 2020	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Medical Countermeasure	Applicant	Key Dates	Indication
Medline Powder-Free Light Blue Nitrile Exam Gloves (Tested for Use with Chemotherapy Drugs)	Medline Industries, Inc.	• Received May 27, 2020 • Cleared September 18, 2020	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Microflex Nitrile Patient Examination Gloves with Aloe and Chamomile	Ansell Healthcare Products LLC	• Received March 13, 2020 • Cleared June 19, 2020	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Modular Toga	Operating Room Innovations, Inc.	• Received April 13, 2020 • Cleared August 5, 2020	Operating Room Innovation's Modular Toga are components of a personal protection system and are intended to protect the patient, health care personnel and operating room personnel against contamination, exposure of infectious bodily fluids, the transfer of microorganisms and particulate material.
Motex Anti-Fog Surgical Face Mask	Modern Healthcare Corp	• Received June 9, 2020 • Cleared August 26, 2020	The Motex Anti-Fog Surgical Face Mask is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.
Non-Sterile, Powder Free Nitrile Examination Gloves, Low Dermatitis Potential, and Tested for use with Chemotherapy Drugs Blue-AC	YTY Industry (Manjung) Sdn Bhd	• Received February 24, 2020 • Cleared May 1, 2020	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Medical Countermeasure	Applicant	Key Dates	Indication
Nitrile Powder Free Examination Gloves with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	Hartalega NGC Sdn. Bhd	• Received June 29, 2020 • Cleared August 25, 2020	Nitrile Powder Free Examination Gloves with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate. These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Fusion Dark Grey)	Hartalega Ngc Sdn. Bhd	• Received June 8, 2020 • Cleared August 5, 2020	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Fusion Dark Grey) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Blue), Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black)	Hartalega NGC Sdn. Bhd.	• Received January 3, 2020 • Cleared April 6, 2020	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It Is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.
Non-sterile, Powder-Free Nitrile Examination Glove Tested for use with Chemotherapy Drugs and Fentanyl	Sri Trang Gloves (Thailand) Public Company Limited	• Received March 3, 2020 • Cleared April 9, 2020	This device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Medical Countermeasure	Applicant	Key Dates	Indication
Plain Surgical Mask	AOK Tooling Limited	• Received June 8, 2020 • Cleared September 4, 2020	The Plain Surgical Face Mask is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.
Polychloroprene Powder Free Sterile Surgical Gloves, Low Dermatitis Potential and Tested for Use with Chemotherapy Drugs	PT. Medisafe Technologies	• Received June 29, 2020 • Cleared September 16, 2020	This surgeon's glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. This glove is also tested for use with Chemotherapy Drugs.
Polyisoprene Powder Free Surgical Underglove for Use with Chemotherapy Drugs (Blue), Polyisoprene Powder Free Surgical Glove for Use with Chemotherapy Drugs (Natural)	Hartalega SDN. BHD	• Received April 3, 2020 • Cleared June 1, 2020	The Polyisoprene Powder Free Surgical Underglove for Use with Chemotherapy Drugs (Blue) is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminations. It is also tested for use against Chemotherapy Drugs.
Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy and Fentanyl) – Regular Cuff; Powder-Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl) - Extended Cuff	Medline Industries, Inc	• Received December 31, 2019 • Cleared August 4, 2020	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Powder Free Nitrile Examination Glove (Aqua Green)	Riverstone Resources SDN BHD	• Received February 10, 2020 • Cleared April 9, 2020	Powder Free Nitrile Examination Glove (Aqua Green) patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

Medical Countermeasure	Applicant	Key Dates	Indication
Power Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl	Comfort Rubber Gloves Industries Sdn. Bhd	• Received October 21, 2019 • Cleared June 19, 2020	The Blue Colored, Powder Free Nitrile Examination Gloves, Non-sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Protective Face Mask for Medical Use	Shandong Shengquan New Material Co., Ltd.	• Received June 8, 2020 • Cleared September 4, 2020	The Protective Face Mask for Medical Use is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.
SensiCare PI and SensiCare PI Micro Surgical Gloves	Medline Industries, Inc.	• Received November 21, 2019 • Cleared April 6, 2020	This surgeon's glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
SensiCare PI Evolution Surgical Glove (Tested for Use with Chemotherapy Drugs)	Medline Industries, Inc	• Received July 2, 2020 • Cleared September 9, 2020	The surgeon's glove is a disposable device made of synthetic rubber latex intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Single-use Surgical Mask	BYD Precision Manufacturer Co.Ltd.	• Received April 7, 2020 • Cleared August 26, 2020	The Single-use Surgical Masks (Model: FE2311) are intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.

Medical Countermeasure	Applicant	Key Dates	Indication
Single-Use Surgical Mask With Ear Loop	Qiqihar Hengxin Medical Supplies, Ltd.	• Received June 22, 2020 • Cleared September 17, 2020	The Single-Use Surgical Mask with Ear Loop is intended to be worn to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device(s), provided non-sterile. Model: M and L, blue color, and Level 2 barrier level as ASTM F2100.
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	Hartalega SDN. BHD.	• Received June 8, 2020 • Cleared August 5, 2020	The Sterile Nltrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate. The gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
Surgical Face Mask	Jiangxi 3L Medical Products Group Co., Ltd	• Received August 11, 2020 • Cleared September 25, 2020	The surgical face mask is intended to be worn to protect both the patient and health care personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Surgical Face Mask	Mexpo International Inc	• Received March 31, 2020 • Cleared April 23, 2020	When properly worn, the surgical face masks are intended to protect both patient and health care workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.
Surgical Gown	Shandong Kangli Medical Equipment Technology Co., Ltd.	• Received September 17, 2019 • Cleared May 22, 2020	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns meet the requirements for Level 3 classification.

Medical Countermeasure	Applicant	Key Dates	Indication
Surgical Mask	C & S Paper Yunfu Co., Ltd.	• Received July 7, 2020 • Cleared August 12, 2020	The Surgical Masks are intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Surgical Mask-Model Number CW01	Hunan Heng Chang Pharmaceutical Co., Ltd.	• Received August 19, 2020 • Cleared September 8, 2020	The Surgical Masks are intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile/sterile.
Synthetic Nitrile Patient Exam Gloves, Powder Free, Blue, Tested for Use w/Chemotherapy Drug	Anhui Intco Medical Products Co., Ltd	• Received January 16, 2020 • Cleared August 20, 2020	The synthetic nitrile patient examination gloves, powder free, blue color and tested for use with chemotherapy drugs are disposable devices intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. The glove was tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Other Devices			
Aer X	3B Medical Inc.	• Received February 28, 2020 • Cleared July 24, 2020	The Aer X oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Aer X may be used in home, institution, vehicle and various mobile environments.
Aerus Medical Guardian, model F170A	Aerus Medical LLC	• Received May 6, 2020 • Cleared June 17, 2020	The Aerus Medical Guardian, model F170A is a device intended for medical purposes that is used for the reduction of *Staphylococcus epidermidis* and *Erwinia herbicola* bacteria, MS2 and Phi-X174 viruses and *Aspergillus niger* fungal spores and *Bacillus globigii* bacterial spores from the air in a temperature-controlled professional health care environment of 70~71°F, 40~45% RH.

Medical Countermeasure	Applicant	Key Dates	Indication
Aluna	Knox Medical Diagnostics, Inc.	• Received November 29, 2019 • Cleared March 25, 2020	Aluna is intended for monitoring FEV1 (Forced exhalation in the first second) and Peak Expired Flow Rate (PEF) for home use. The device is designed for children 5 years of age or older, adolescent and adult subjects. Additionally, the device may be used by clinicians for in-office monitoring.
BD SoloShot Mini Syringe/BD Auto Disable Syringe	Becton Dickinson	• Received May 7, 2020 • Cleared July 15, 2020	The BD SoloShot Mini Syringe/ BD Auto Disable Syringe is intended for aspiration and injection of fluids.
The C100 Contactless Breathing Monitor	Circadia Technologies Ltd.	• Received February 24, 2020 • Cleared June 24, 2020	The Circadia C100 System is indicated for both contactless spot checking and continuous measurement of respiratory rate data as part of a vital signs assessment. The system records, transmits, and displays respiratory rate from multiple connected devices for retrospective analysis only. The system is intended to be used under the care of clinicians and medically qualified personnel.
Capnostream 35 Portable Respiratory Monitor	Oridion Medical 1987 Ltd.	• Received March 6, 2020 • Cleared April 27, 2020	The Capnostream 35 monitor is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused. The Capnostream 35 monitor also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up. The OxiMax SPD alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs. The Nellcor respiration rate parameter is intended for the continuous, non-invasive monitoring of respiration rate in adult patients in hospitals and hospital-type facilities. Other than the OxiMax SPD alert and Nellcor respiration rate features, the device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

Medical Countermeasure	Applicant	Key Dates	Indication
Care Orchestrator with Home Sleep Testing	Respironics, Inc.	• Received June 1, 2020 • Cleared September 25, 2020	Care Orchestrator is intended to support clinicians by tracking data on patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. Care Orchestrator provides remote patient data collection & viewing and is intended to be used by health care representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. In addition, Care Orchestrator can be used for analysis (automatic and manual scoring), display, retrieval, summarization, and report generation of data received from compatible monitoring devices used to categorize sleep-related events that help aid in the diagnosis of sleep-related disorders. The Home Sleep Testing function of Care Orchestrator is indicated for Adult use only. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.
Disposable SpO2 Sensor	Shenzhen Changke Connect Electronics Co., Ltd.	• Received January 13, 2020 • Cleared March 13, 2020	The Disposable SpO2 Sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adults in hospital environment.
DreamStation 2 System, DreamStation 2 Advanced System	Respironics, Inc.	• Received February 27, 2020 • Cleared July 10, 2020	The DreamStation 2 CPAP/DreamStation 2 Auto CPAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs). It is for use in the home or hospital/institutional environment.
ExSpiron 2Xi	Respiratory Motion	• Received September 20, 2019 • Cleared December 17, 2019	ExSpiron 2Xi is indicated for use by health care professionals in health care facilities, such as postoperative care and critical care units, to monitor breathing in patients at least one year of age. ExSpiron 2Xi is a non-invasive monitor that graphically displays lung volume against time and reports an approximate value of: minute ventilation (MV), tidal volume (TV), and respiratory rate (RR). ExSpiron 2Xi measurements are used as an adjunct to other clinical information.
Game Ready GRPro 2.1 System	Game Ready	• Received August 6, 2019 • Cleared October 29, 2019	The Game Ready GRPro 2.1 System is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed health care professionals in hospitals, outpatient clinics, athletic training settings or home settings.

Medical Countermeasure	Applicant	Key Dates	Indication
GE ApexPro CH SpO2 - Nellcor Cable, GE ApexPro FH SpO2 - Nellcor Cable	Covidien llc	• Received May 1, 2020 • Cleared July 20, 2020	The Nellcor Cable is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for use with neonate, pediatric, and adult patients during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.
H500 Multi-Sensing Oximetry System	Nonin Medical, Inc.	• Received October 15, 2019 • Cleared June 29, 2020	The Nonin Medical CO-Pilot™ Model H500 Multi-Sensing Oximetry System is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO2). This device is not meant for sole use in clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms. For %SpO2 and pulse rate, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients who are well or poorly perfused, during both motion and non-motion conditions in professional health care facilities, mobile, and EMS settings. For %rSO2, the H500 System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients in professional health care facilities, mobile, and EMS settings. For %COHb and %MetHb, the H500 System is intended for spot-checking, multiple spot-checks to observe change, and/or measuring during clinician assessment of adult and pediatric patients in professional health care facilities, mobile, and emergency medical service (EMS) settings.
Hamilton-G5	Hamilton Medical AG	• Received November 22, 2019 • Cleared May 4, 2020	The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transportation outside the hospital or for use in the home environment.

Medical Countermeasure	Applicant	Key Dates	Indication
Invacare Perfecto$_2$V Oxygen Concentrator	Invacare Corporation	• Received April 3, 2020 • Cleared August 8, 2020	The Invacare Perfecto$_2$V Oxygen Concentrator is intended for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. For flow rates below 1 liter per minute use with Invacare Pediatric Flowmeter accessory. It is not intended to sustain or support life.
KeraStat Cream	KeraNetics	• Submitted September 3, 2019 • Cleared July 16, 2020	KeraStat Cream is intended to maintain a moist wound environment, and is indicated for management of a number of partial thickness skin wounds such as: partial thickness (first and second degree) burns, severe sunburns, superficial injuries, cuts, abrasions, and incisions/surgical wounds. Under the direction of a health care professional, KeraStat Cream may also be used in the management of dry, light, and moderately exuding partial thickness wounds including: pressure (stage I-II) ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites, and grafts. KeraStat Cream is not indicated for full thickness or third degree burns. This device will be available by prescription.
Leadtek Fingertip Pulse Oximeter	Leadtek Research Inc.	• Received December 3, 2019 • Cleared April 27, 2020	The Leadtek Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during nomotion condition.
Masimo Rad-97 Pulse CO-Oximeter and Accessories	Masimo Corporation	• Received December 26, 2019 • Cleared August 10, 2020	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring. **See the 510(k) summary for complete indications for use.**

Medical Countermeasure	Applicant	Key Dates	Indication
Masimo Rad-G Pulse Oximeter, Masimo Rad-G YI sensor, Masimo Rad-G Reusable sensor	Masimo Corporation	• Received June 29, 2020 • Cleared September 24, 2020	The Rad-G Pulse Oximeter and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), PR, and Pleth Respiration Rate (RRp). The Rad-G Pulse Oximeter and Accessories are indicated for noninvasive spot-checking or continuous monitoring of SpO2 and PR of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments. The Rad-G Pulse Oximeter and Accessories are indicated for the spot-checking or continuous monitoring of RR the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.
Masimo Rad-97 Pulse CO-Oximeter and Accessories, Masimo Radical-7 Pulse CO-Oximeter and Accessories, Masimo Radius-7 Pulse CO-Oximeter and Accessories	Masimo Corporation	• Received November 25, 2019 • Cleared February 27, 2020	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring. **See 510(k) summary for full indication**.
Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor	Surgical Instrument and Savings Inc (dba Medline ReNewal)	• Received June 22, 2020 • Cleared July 22, 2020	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor Model MAXNAR is indicated for single patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring is required for adult patients as indicated in the sensor directions for use. This device is for prescription use only.
Molekule Air Pro RX	Molekule	• Received February 28, 2020 • Cleared April 15, 2020	The Molekule Air Pro RX air purifier is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation.
Nuvo Nano Portable Oxygen Concentrator	Nidek Medical Products, Inc.	• Received September 26, 2019 • Cleared May 7, 2020	The Nuvo Nano Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel / mobile environments.

Medical Countermeasure	Applicant	Key Dates	Indication
Owgels Oxygen Concentrator	Guangzhou Life Light Electronic Technology Co., Ltd	• Received July 12, 2019 • Cleared July 20, 2019	The Owgels Oxygen Concentrator is intended to be used by patients with respiratory disorders who require supplemental oxygen. A high concentration of supplemental oxygen is supplied and a nasal cannula is used to channel oxygen from the concentrator to the patient. The Owgels Oxygen Concentrator can be used in a home, institution environments. The Owgels Oxygen Concentrator does not nor is it intended to sustain or support life. The device is intended for use in adults.
OxSAT 100	S.L.P. Ltd.	• Received June 14, 2019 • Cleared April 9, 2020	The SLP OxSAT 100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO2), PR, and plethysmographic data to a compatible polysomnography (PSG) and/or home sleep test (HST) device. It is not intended for use with low perfused patients.
Oxxiom	True Wearables, Inc.	• Received March 3, 2020 • Cleared July 3, 2020	The Oxxiom Pulse Oximetry System is a wireless, fully disposable, single-use device indicated for measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and PR. It may be used for spot checking, intermittent monitoring, and/or data collection of patients 12 years and older in low acuity settings in facilities such as hospitals, clinics, and doctor's offices. It can also be used in home health care settings under prescription use. It is not intended for continuous monitoring.
Protego Antimicrobial Wound Dressing	Global Health Solutions (DBA Turn Therapeutics)	• Received December 28, 2018 • Cleared October 11, 2019	A single-use, sterile, antimicrobial gauze dressings are impregnated with a petrolatum-based wound care emulsion, providing broad-spectrum antimicrobial protection against bacteria, fungi, and yeasts.
Pulse Oximeter	Shenzhen Aeon Technology Co., Ltd.	• Received February 19, 2020 • Cleared September 23, 2020	The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and PR. This portable device is indicated for use in adult patients in clinical institution and home environments.
QuikClot Control+	Z-Medica, LLC	• Received January 23, 2020 • Cleared April 23, 2020	QuikClot Control+ Hemostatic Dressing is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Medical Countermeasure	Applicant	Key Dates	Indication
Reusable and Disposable SpO2 Sensors	Xinkang Medical Instrument Co. Ltd.	• Received May 21, 2020 • Cleared August 19, 2020	The Reusable and Disposable SpO2 Sensors are indicated for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensors are intended to be used in hospital settings where patient care is offered by qualified health care personnel.
Safey Pocket Spirometer	Safey Medical Devices Pvt Ltd	• Received April 16, 2020 • Cleared July 30, 2020	Safey Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home health care environment.
Servo-air 4.0 Ventilator System	Maquet Critica Care AB	• Received September 20, 2019 • Cleared June 18, 2020	The Servo-air ventilator system is intended for respiratory support, monitoring and treatment of pediatric and adult patients to be used only by health care providers to be used only in professional health care facilities and for transport within these facilities.
Safey Peak Flow Meter	Safey Medical Devices Pvt Ltd	• Received March 30, 2020 • Cleared July 30, 2020	Safey Peak Flow Meter is intended to measure PEF and Forced Expiratory Volume in one second (FEV1) in home health care environment. The device is designed for children greater than five years of age, adolescent and adult subjects.
Vitalograph Model 2120 In2itive eDiary	Vitalograph Ireland Ltd.	• Received March 3, 2020 • Cleared July 27, 2020	The Vitalograph Model 2120 In2itive eDiary device is a battery-operated spirometer which measures three basic patient respiratory parameters (forced vital capacity [FVC], maximal voluntary ventilation [MVV] and vital capacity [VC]). The Vitalograph Model 2120 In2itive eDiary is a handheld spirometer designed for lung function testing in a variety of environments such as hospital wards, health centers and private homes. It is intended for adults and pediatric patients, 5 years and older.

APPENDIX 3: MCM-RELATED GUIDANCE ISSUED IN FY 2020[ab]

In FY 2020, FDA issued more than 60 COVID-19-related guidances, to provide timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid response efforts to the COVID-19 public health emergency.[122] Only MCM-related guidances are included below; the full list of COVID-19-related guidance documents is **available on the FDA website**.[123] Note that some COVID-19 guidance documents may have been updated once or more since issuance. The date listed in this table for all documents refers to the most recent update available at the end of FY 2020 (September 30, 2020). Some guidances may be temporary, that is, only in effect during the COVID-19 public health emergency.

Date	Guidance Type	Guidance Name	Purpose
November 15, 2019	Final	Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention Guidance for Industry (**link**)	To assist sponsors in the clinical development of drugs for treatment or prevention of smallpox (variola virus) infection. Clinical efficacy trials of drugs for treating or preventing smallpox are not feasible and challenge studies in healthy subjects are unethical; therefore, drugs for these indications should be developed and approved under the regulations commonly referred to as the Animal Rule (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics).
December 12, 2019	Draft	Qualification Process for Drug Development Tools Guidance for Industry and FDA Staff (**link**)	Section 3011 of the Cures Act added new section 507, Qualification of Drug Development Tools (DDTs), to the FD&C Act. This draft guidance meets the Cures Act's mandate to issue guidance on this section-507 qualification process and related Prescription Drug User Fee Act (PDUFA) VI commitments; the draft guidance of the same name issued January 7, 2014, is withdrawn. Specifically, once finalized, this guidance will represent CDER's and CBER's current thinking on taxonomy for biomarkers and other DDTs, and on implementation of section 507 of the FD&C Act with respect to the processes for requestors interested in qualifying DDTs. DDTs are methods, materials, or measures that have the potential to facilitate drug development, including, for example, an animal model used for efficacy testing of MCMs under the Animal Rule.

[ab] This table includes guidance documents designed to address MCM-specific topics and guidance documents that address more general topics considered to have likely relevance to some aspects of MCM development. It is not intended as a comprehensive list of all guidance documents; some product sponsors may find additional relevant documents on the FDA guidance website at **https://www.fda.gov/regulatory-information/search-fda-guidance-documents**

Date	Guidance Type	Guidance Name	Purpose
December 19, 2019	Final	Considerations for the Development of Dried Plasma Products Intended for Transfusion (**link**)	Provides recommendations intended to assist manufacturers, sponsors, and applicants developing dried plasma products intended for transfusion in order to facilitate the availability of safe and effective dried plasma products in the U.S. This guidance provides considerations for the successful development and licensing of dried plasma products and for the approval of devices used to manufacture dried plasma. The guidance includes recommendations on optimal sources of input plasma; manufacturing and product quality, including product characterization; packaging and reconstitution; clinical studies; and device submissions. This guidance finalizes the draft guidance of the same title dated October 2018.
March 22, 2020	Final	Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals (**link**)	To communicate FDA's temporary policy for certain risk evaluation and mitigation strategies requirements for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020.
March 22, 2020	Final	Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability of ventilators as well as other respiratory devices and their accessories during the COVID-19 pandemic.
March 27, 2020	Final	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry (**link**)	FDA issued this guidance to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain drugs and biological products that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of such products.

Date	Guidance Type	Guidance Name	Purpose
March 29, 2020	Final	Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during the COVID-19 public health emergency.
March 30, 2020	Final	Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (**link**)	To help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during the COVID-19 pandemic.
April 2, 2020	Final	Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency (**link**)	To respond to a national public health need and address the urgent and immediate need for blood and blood components, under 21 CFR 640.120(b). FDA expects that the alternative procedures will improve availability of blood and blood components while helping to ensure adequate protections for donor health and maintaining a safe blood supply for patients.
April 4, 2020	Final	Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability of clinical electronic thermometers to address this public health emergency.
April 5, 2020	Final	Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability and remote capabilities of infusion pumps and their accessories for health care professionals during the COVID-19 pandemic.
April 6, 2020	Final	Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability of devices used in extracorporeal membrane oxygenation (ECMO) therapy to address the COVID-19 public health emergency.

Date	Guidance Type	Guidance Name	Purpose
April 13, 2020	Final	Product-Specific Guidances for Chloroquine Phosphate and Hydroxychloroquine Sulfate (**link**)	In anticipation of increased demand for chloroquine phosphate and hydroxychloroquine sulfate, the FDA is taking steps to ensure that adequate supply of these drug products is available by publishing product-specific guidances to support generic drug development for these drugs. The product-specific guidance for chloroquine phosphate clarifies that the product is AA rated in the Approved Drug Products with Therapeutic Equivalence Evaluations publication (Orange Book), meaning that there are no known or suspected bioequivalence problems, and no in vivo studies are necessary. The product-specific guidance for hydroxychloroquine sulfate adds advice about a Biopharmaceutics Classification System-based biowaiver option.
April 16, 2020	Final	Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide a policy to help expand the availability of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020.
April 21, 2020	Draft	Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA (**link**)	Covers emergency-use injectors submitted under a BLA, NDA, or Abbreviated New Drug Application (ANDA). The term “emergency-use injector” means injectors marketed with an emergency-use drug as a prefilled single entity combination product under 21 CFR 3.2(e)(1) or as a co-packaged combination product under 21 CFR 3.2(e)(2). Emergency-use injector includes pen injectors, autoinjectors, or on-body-wearable delivery systems for drugs for emergency treatment of conditions such as anaphylaxis, opioid overdose, poisoning, or severe hypoglycemia.
April 22, 2020	Final	Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency (**link**)	To communicate FDA’s temporary policy regarding the repackaging or combining of propofol drug products by a licensed pharmacist in a State licensed pharmacy, a Federal facility, or an outsourcing facility registered pursuant to section 503B of the FD&C Act (21 U.S.C. 353b).

Date	Guidance Type	Guidance Name	Purpose
April 30, 2020	Final	Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency (**link**)	Due to the COVID-19 pandemic, FDA has been monitoring requests related to provisions of the Drug Supply Chain Security Act (DSCSA) because the provisions may affect the prescription drug supply chain during the COVID-19 outbreak. FDA issued this guidance to clarify the scope of the public health emergency exemption and exclusion under the DSCSA for the duration of the COVID-19 public health emergency, to help ensure adequate distribution of finished prescription drug products throughout the supply chain to combat COVID-19. In addition, this guidance announces FDA's policy regarding the exercise of its discretion in the enforcement of authorized trading partner requirements under section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act for certain distributions during the COVID-19 public health emergency involving other trading partners that may not be authorized trading partners.
May 8, 2020	Final	Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (**link**)	Provides recommendations to industry regarding postmarketing adverse event reporting for drugs, biologics, medical devices, combination products, and dietary supplements during a pandemic. FDA anticipates that during a pandemic, industry and FDA workforces may be reduced because of high employee absenteeism while reporting of adverse events related to widespread use of medical products indicated for the treatment or prevention of the pathogen causing the pandemic may increase. The extent of these possible changes is unknown. This guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for medical products and dietary supplements during a pandemic.
May 11, 2020	Final	Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (**link**)	To provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. Rapid detection of COVID-19 cases in the U.S. requires wide availability of testing to control the emergence of this rapidly spreading, severe illness. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the U.S.

Date	Guidance Type	Guidance Name	Purpose
May 11, 2020	Final	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention (**link**)	To assist sponsors in the clinical development of drugs for the treatment or prevention of COVID-19. (Preventative vaccines and convalescent plasma are not within the scope of this guidance.)
May 11, 2020	Final	COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products (**link**)	To provide general considerations to assist sponsors in preparing pre-IND meeting requests for COVID-19 related drugs for the duration of the COVID-19 public health emergency. As described in further detail in this guidance, FDA recommends that sponsors initiate all drug development interactions for COVID-19 related drugs through IND meeting requests.
May 21, 2020	Final	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry (**link**)	To communicate FDA's temporary policy for the compounding of certain human drug products for hospitalized patients by State-licensed pharmacies and Federal facilities, including hospital and health system pharmacies, that are not registered with FDA as outsourcing facilities for the duration of the COVID-19 public health emergency.
May 21, 2020	Final	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (**link**)	To communicate FDA's temporary policy for the compounding of certain human drug products for hospitalized patients by outsourcing facilities that have registered with FDA under section 503B of the FD&C Act (21 U.S.C. 353b). FDA generally tries to address potential and actual drug shortages by working through the global pharmaceutical supply chain rather than relying on compounded drugs and focuses on restoring supplies of FDA-approved drugs. However, in light of unprecedented disruptions to, and demands on, the global pharmaceutical supply chain as a result of the COVID-19 pandemic, and in order to respond to evolving regional conditions, additional flexibility is temporarily needed to ensure that treatment options are available when hospitals are unable to obtain FDA-approved drugs used for hospitalized patients with COVID-19.

Date	Guidance Type	Guidance Name	Purpose
May 26, 2020	Final	Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) (**link**)	To provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care personnel for the duration of the COVID-19 public health emergency.
May 26, 2020	Final	Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To provide recommendations for sponsors of decontamination and bioburden reduction systems about what information should be included in a pre-EUA and/or EUA request to help facilitate FDA's efficient review of such request. This guidance provides these recommendations based on the device's intended use with respect to the level (tier) of decontamination or bioburden reduction, based on the sponsor's available data. Decontamination and bioburden reduction systems play an important role in the ongoing efforts to help address shortages of surgical masks and respirators intended for a medical purpose during COVID-19 or reduce the bioburden of surgical masks and filtering facepiece respirators (including N95 respirators) used as PPE by health care personnel for the duration of the COVID-19 public health emergency.
May 26, 2020	Final	Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers (**link**)	To provide answers to frequently asked questions about regulatory and policy issues related to drug development for the duration of the COVID-19 public health emergency.
June 2, 2020	Final	Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators (**link**)	During the COVID-19 public health emergency, the Agency has received a substantially increased volume of individual patient expanded access requests for COVID-19 investigational drugs. Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek clarity regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under 21 CFR Part 56. Therefore, FDA issued this guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing expanded access submissions for individual patient access to investigational drugs for treating COVID-19.

Date	Guidance Type	Guidance Name	Purpose
June 5, 2020	Final	Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) (**link**)	To provide a policy to help expand the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and health care provider contact and exposure to COVID-19 for the duration of the COVID-19 public health emergency.
June 16, 2020	Final	Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry (**link**)	To provide recommendations on statistical considerations to address the impact of COVID-19 on meeting trial objectives for clinical trials conducted during the duration of the COVID-19 public health emergency. The COVID-19 pandemic has impacted clinical development and ongoing clinical trials across investigational product areas. Public health measures to control the virus may impact the ability to collect data, for example, if trial participants are not able to visit clinical sites for endpoint assessments. The guidance outlines considerations for the statistical analysis of the primary and key secondary endpoints in a trial affected by COVID-19 to help ensure that the trial will provide interpretable findings with correct statistical quantification of uncertainty.
June 19, 2020	Final	Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) (**link**)	To implement section 506J of the FD&C Act (21 U.S.C. 351 et seq.), as added by section 3121 of the CARES Act, as it relates to device shortages and potential device shortages occurring during the COVID-19 pandemic, for the duration of the COVID-19 public health emergency.
June 19, 2020	Final	Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing (**link**)	To provide recommendations to drug and biological product manufacturers regarding manufacturing controls to prevent contamination of drugs, risk assessment of SARS-CoV-2 as it relates to drug safety or quality, and continuity of manufacturing operations. This policy is intended to remain in effect only for the duration of the COVID-19 public health emergency.

Date	Guidance Type	Guidance Name	Purpose
June 22, 2020	Final	Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers (**link**)	To provide answers to frequently asked questions about regulatory and policy issues related to device development for the duration of the COVID-19 public health emergency.
June 30, 2020	Final	Development and Licensure of Vaccines to Prevent COVID-19 (**link**)	To assist sponsors in the clinical development and licensure of vaccines for the prevention of COVID-19.
July 20, 2020	Final	Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (**link**)	To help facilitate the availability of devices for use in transporting certain clinical specimens, including transport media that can be used to transport certain clinical specimens for use with molecular RT-PCR SARS-CoV-2 assays or antigen-detection diagnostic SARS-CoV-2 assays for the duration of the COVID-19 public health emergency.
September 2, 2020	Final	Investigational COVID-19 Convalescent Plasma (**link**)	To provide recommendations to health care providers and investigators on the use of COVID-19 convalescent plasma[ac] or investigational convalescent plasma during the public health emergency. The guidance also provides recommendations to blood establishments on collection. We also describe FDA's interim compliance and enforcement policy regarding the IND requirements for the use of investigational convalescent plasma. This document was initially issued in April 2020, and updated in May 2020.
September 10, 2020	Final	Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency (**link**)	To help drug and biological product manufacturers during the COVID-19 public health emergency plan and prioritize current Good Manufacturing Practices (cGMP) activities as they transition from operations impacted by the public health emergency to normal manufacturing operations. This guidance describes how to evaluate and prioritize the remediation of cGMP activities that were necessarily delayed, reduced, or otherwise modified during the public health emergency in order to maintain production and the drug supply.

[ac] On August 23, 2020, FDA issued an EUA for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. FDA recognizes that while COVID-19 convalescent plasma may be used under an EUA consistent with the authorization, COVID-19 convalescent plasma may also be used under an IND. For the purposes of this guidance, the term "COVID-19 convalescent plasma" refers to the convalescent plasma authorized under the EUA, while the term "investigational convalescent plasma" refers to convalescent plasma that does not meet all the conditions of the EUA and/or is being used under an IND.

Date	Guidance Type	Guidance Name	Purpose
September 14, 2020	Final	Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment (**link**)	To provide sponsors and investigators with considerations for approaches on how common COVID-19-related symptoms can be measured and analyzed in clinical trials evaluating drugs or biological products for the prevention or treatment of COVID-19 in outpatient adult and adolescent subjects, for the duration of the COVID-19 public health emergency.
September 21, 2020	Final	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (**link**)	To provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity for the duration of the COVID-19 public health emergency. The appendix to this guidance further explains those general considerations by providing answers to questions that the Agency has received about conducting clinical trials during the COVID-19 public health emergency.

APPENDIX 4: KEY MCM-RELATED MEETINGS HELD IN FY 2020[ad]

Due to COVID-19, FDA took steps to ensure the agency was able to continue our vital public health mission in FY 2020. Where possible the agency leveraged technology to host meetings allowing for remote participation. We also continue to explore meeting platforms and formats, including pre-recorded presentations. This continued assessment is necessary as we respond to the challenges presented by the pandemic. The format for any meeting will be based on the discussion, advice, and recommendation that FDA needs from the committee as well as the requirements under the Federal Advisory Committee Act, if applicable.

Date	Type of Event	Event Name	Purpose
October 9, 2019	Public meeting	Vaccines and Related Biological Products Advisory Committee (VRBPAC) (**link**)	To discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2020 southern hemisphere influenza season.
November 8, 2019	Public meeting	Vaccines and Related Biological Products Advisory Committee (VRBPAC) (**link**)	To discuss and make recommendations on the development of chikungunya vaccines.
November 18, 2019	Public workshop	Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making (**link**)	To discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions.
November 18-19, 2019	Public workshop	Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development (no link available)	Co-sponsored by FDA, the Infectious Diseases Society of America (IDSA), NIAID, and Pew, this workshop will bring together a diverse array of subject matter experts in the fields of infectious diseases (ID), academics and industry and other government bodies to better understand the current state of U.S.-based ID trials and how to enhance enrollment and research in such trials.

[ad] This table includes FDA-sponsored meetings intended to address MCM-specific topics, or more general FDA-sponsored meetings that may be relevant to some aspects of MCM development. In some cases, FDA may have provided funding to support certain meetings hosted by others (e.g., NASEM).

Date	Type of Event	Event Name	Purpose
November 22, 2019	Public meeting	Blood Products Advisory Committee meeting (**link**)	To discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee heard presentations on available characterization and functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee also discussed the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.
February 3, 2020	Public workshop	Advancing EUA IVD Products Toward Full Marketing Status (**link**)	Hosted by FDA and the Medical Device Innovation Consortium (MDIC), this workshop explored key considerations for using real world data (RWD) to generate real world evidence (RWE) to help support IVD products available under EUA to advance to full marketing status.
March 2, 2020	Webinar	Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (**link**)	For laboratories certified to perform high-complexity testing under CLIA, and others interested in learning more about this guidance.
March 4, 2020	Public meeting	Vaccines and Related Biological Products Advisory Committee (VRBPAC) (**link**)	To discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2020 to 2021 influenza season
March 5, 2020	Public workshop	Advancing Animal Models for Antibacterial Drug Development (**link**)	Hosted by FDA, NIH, and BARDA to discuss progress and challenges in the development and advancement of various animal models for serious infection.
March 6, 2020	Webinar	Virtual Town Hall - Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (**link**)	To help answer technical questions about development and validation of molecular tests for SARS-CoV-2 and the recently-issued guidance.

Date	Type of Event	Event Name	Purpose
March 12, 2020	Webinar	FDA Grand Rounds: Modernization of Pharmaceutical Manufacturing through the Adoption of Advanced Technology (**link**)	To provide an overview of these advanced manufacturing technologies methodologies, discuss the many steps the FDA is taking to help realize the potential of advanced manufacturing, and highlight success stories of successful implementation of advanced manufacturing which holds great potential for improving the quality assurance of drugs.
March – September 2020 (weekly)	Webinar series	Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation (**link**)	To help answer technical questions about the development and validation of tests for SARS-CoV-2.
April 30, 2020	Webinar	SBIA Webinar: Conducting Clinical Trials During the COVID-19 Public Health Emergency (**link**)	To provide timely guidance to support continuity and response efforts to the COVID-19 public health emergency, and discuss the FDA Guidance on Conducting Clinical Trials of Medical Products during the COVID-19 Public Health Emergency.
May 11, 2020	Webinar	Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (**link**)	To discuss and answer questions about the immediately in effect guidance Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency.
May 15, 2020	Webinar	Virtual Town Hall - 3D Printed Swabs (**link**)	For researchers, clinical laboratories, and commercial manufacturers to discuss the production and use of 3D-printed swabs during the COVID-19 public health emergency, a collaboration between the FDA, the VA Innovation Ecosystem, and the NIH 3D Print Exchange.
June 9, 2020	Webinar	CURE ID: Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-19 (**link**)	To demonstrate **CURE ID**, a mobile app and web platform developed by FDA and NCATS/NIH, that gives the global clinical community the opportunity to report novel uses of existing drugs for patients with difficult-to-treat infectious diseases, including COVID-19, and explain the features and goals of the platform.

Date	Type of Event	Event Name	Purpose
June – September 2020 (every two weeks)	Webinar series	Webinar Series - Respirators and Other Personal Protective Equipment (PPE) for Health Care Personnel Use During the COVID-19 Pandemic (**link**)	To share information and answer questions about EUAs for respirators, importing respirators, and overall FDA actions to help assure health care personnel on the front lines have the necessary supplies of respirators to meet the demand. Hosted with speakers from FDA, the CDC National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA).
June 11, 2020	Webinar	A Pandemic and a Call to Action for One Health: The FDA One Health Initiative (**link**)	To explain the One Health Concept and the FDA One Health Initiative, and highlight the benefits of One Health and how FDA is operationalizing One Health actions Agency-wide.
August 4, 2020	Public workshop (virtual)	Development Considerations of Antifungal Drugs to Address Unmet Medical Need (**link**)	To discuss unmet medical needs of invasive molds and *Candida auris* and clinical trial design considerations for developing new therapies.
August 5, 2020	Public workshop (virtual)	Coccidioidomycosis (Valley Fever): Considerations for Development of Antifungal Drugs (**link**)	To discuss coccidioidomycosis, current state and clinical disease and trial design considerations for developing antifungal drugs.
September 10, 2020	Webinar	Advancing the Science of Real-World Data to Address the COVID-19 Pandemic (**link**)	The FDA is applying data from diverse sources to inform its response to COVID-19, including sources that were already available to the agency, such as Sentinel, Biologics Effectiveness and Safety System (BEST), and National Evaluation System for health Technology (NEST). The urgency of addressing the COVID-19 pandemic has demanded that we expand our work to identify, access and analyze new datasets to widen the breadth of the information available. This work is being done in collaboration with partners in the U.S. government, academia and industry. This webinar discussed that work.
September 17-18, 2020	Public workshop (virtual)	Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines (**link**)	To exchange information with stakeholders from industry, academia, and government about the scientific, clinical, and regulatory challenges and opportunities in using RWE to assess the effectiveness of preventive vaccines.

APPENDIX 5: ACRONYMS

AAMI	Association for the Advancement of Medical Instrumentation
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
AMR	Antimicrobial resistance
ANDA	Abbreviated New Drug Application
AR	Antibiotic resistance
ASTM	American Society for Testing and Materials
ATCC	American Type Culture Collection
ARS	Acute radiation syndrome
ASPR	Assistant Secretary for Preparedness and Response (HHS)
BAA	Broad Agency Announcement
BARDA	Biomedical Advanced Research and Development Authority
BEST	Biologics Effectiveness and Safety System
BLA	Biologics License Application
BSL	Biosafety level
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBRN	Chemical, biological, radiological, and nuclear
CBER	FDA Center for Biologics Evaluation and Research
CDC	U.S. Centers for Disease Control and Prevention
CDER	FDA Center for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
CDRC	CURE Drug Repurposing Collaboratory
CDRH	FDA Center for Devices and Radiological Health
CEPI	Coalition for Epidemic Preparedness Innovations
cGMP	Current good manufacturing practices
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus disease 2019 (caused by SARS-CoV-2)
C-Path	Critical Path Institute
CPAP	Continuous positive airway pressure
CRADA	Cooperative Research and Development Agreement
CRP	Critical Reagents Program
CTAP	Coronavirus Treatment Acceleration Program
DARPA	Defense Advanced Research Projects Agency
DDT	Drug Development Tool
DHS	U.S. Department of Homeland Security
DNA	Deoxyribonucleic acid
DoD	U.S. Department of Defense
DRC	Democratic Republic of the Congo
DSCSA	Drug Supply Chain Security Act

DTRA	Defense Threat Reduction Agency
ECMO	Extracorporeal membrane oxygenation
EMS	Emergency medical service
EPA	Environmental Protection Agency
EUA	Emergency Use Authorization
EVD	Ebola virus disease
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
FDA-ARGOS	FDA Database for Regulatory Grade Microbial Sequences
FDP	Freeze-dried plasma
FEMA	Federal Emergency Management Agency
FEV1	Forced Expiratory Volume in one second
FIND	Foundation for Innovative New Diagnostics
FFR	Filtering facepiece respirator
FTE	Full-time equivalent
FVC	Forced vital capacity (a lung function test)
FY	Fiscal year
GCP	Good clinical practice
GHSA	Global Health Security Agenda
GHSI	Global Health Security Initiative
GloPID-R	Global Research Collaboration for Infectious Diseases Preparedness
H-ARS	Hematopoietic syndrome of acute radiation syndrome
HCT/P	Human cells, tissues, and cellular and tissue-based products
HHS	U.S. Department of Health and Human Services
HHS-CIADM	Department of Health and Human Services Centers for Innovation in Advanced Development and Manufacturing
HST	Home sleep test
ICMRA	International Coalition of Medicines Regulatory Authorities
ID	Infectious diseases
IDE	Investigational Device Exemption
IDSA	Infectious Diseases Society of America
IgM	Immunoglobulin M
IHR	International Health Regulations
IND	Investigational New Drug
IRB	Institutional Review Board
IVD	*In vitro* diagnostic
JEE	Joint External Evaluation
JIC	Joint Information Center
JMEDICC	Joint Mobile Emerging Disease Intervention Clinical Capability
JPC-1/MSIS	Joint Program Committee-1/Medical Simulation and Information Sciences
JRAC-SDC	Joint Rapid Acquisition Cell–Screening and Diagnostics Capability
LLNL	Lawrence Livermore National Laboratory
MCM	Medical countermeasure
MCM ADM	DoD Medical Countermeasures Advanced Development and Manufacturing
MCMi	FDA Medical Countermeasures Initiative
MDR	Multi-drug resistant

MDIC	Medical Device Innovation Consortium
MERS-CoV	Middle East Respiratory Syndrome coronavirus
mg	Milligram
MIBI	Multiplexed ion beam imaging
MOU	Memorandum of Understanding
MPS	Microphysiological systems
MRI	Magnetic resonance imaging
MV	Minute ventilation (the volume of gas inhaled or exhaled from a person's lungs per minute)
MVV	Maximal voluntary ventilation (total volume of air exhaled during 12 seconds of rapid, deep breathing)
NAAT	Nucleic acid-based amplification test
NACCHO	National Association of County and City Health Officials
NASA	National Aeronautics and Space Administration
NASEM-HMD	National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NDA	New Drug Application
NEST	National Evaluation System for health Technology
NETCCN	National Emergency Telecritical Care Network
NGDS	Next-Generation Diagnostic System
NGO	Non-governmental organization
NGS	Next-generation sequencing
NIAID	National Institute of Allergy and Infectious Diseases
NICBR	National Interagency Confederation for Biological Research
NIH	U.S. National Institutes of Health
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NPS	Nasopharyngeal swab
NSC	National Security Council
OCET	FDA Office of Counterterrorism and Emerging Threats
ODI	Oxygen desaturation index
ONC	Office of the National Coordinator for Health Information Technology
OSEL	FDA CDRH Office of Science and Engineering Labs
OSHA	Occupational Safety and Health Administration
PAHPAIA	Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
PBMC	Peripheral blood mononuclear cell
PBPK	Physiologically based pharmacokinetic
PCR	Polymerase chain reaction
PDUFA	Prescription Drug User Fee Act
PEF	Peak expired flow rate
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHS Act	Public Health Service Act
PMA	Premarket Approval
PPE	Personal protective equipment

PPP	Public private partnership
PR	Pulse rate
PRV	Priority review voucher
PSG	Polysomnography
Rad/nuc	Radiological/nuclear
RDT	Rapid diagnostic test
REMS	Risk Evaluation and Mitigation Strategies
RMP	Regulatory Management Plan
RNA	Ribonucleic acid
RPP	Respiratory pathogen panel
RR	Respiratory rate
RRp	Photoplethysmogram respiration rate
RT-PCR	Reverse transcriptase-polymerase chain reaction
RWD	Real-world data
RWE	Real-world evidence
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SDTM	Study Data Tabulation Model
SENDIG	Standard for Exchange of Nonclinical Data Implementation Guide
SHIELD	Systemic Harmonization and Interoperability Enhancement for Laboratory Data
SLEP	Shelf-Life Extension Program
SLTT	State, local, tribal and territorial
sNDA	Supplemental New Drug Application
SNS	Strategic National Stockpile
SPA	Special Protocol Assessment
SpO2	Functional oxygen saturation of arterial hemoglobin
TATRC	Telemedicine and Advanced Technology Research Center
TBI	Traumatic brain injury
TTFED	Tri-Agency Task Force for Emergency Diagnostics
TV	Tidal volume (the amount of air that moves in or out of the lungs with each respiratory cycle)
U.S.	United States
USAMRDC	U.S. Army Medical Research and Development Command
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USDA	U.S. Department of Agriculture
USG	United States government
USGS	U.S. Geological Survey
UTMB	University of Texas Medical Branch
VA	U.S. Department of Veterans Affairs
VC	Vital capacity (a lung function test)
VRBPAC	Vaccines and Related Biological Products Advisory Committee
WHO	World Health Organization

ENDNOTES

[1] For a listing of MCM-related legislation, see: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation**

[2] Detailed information on FDA's MCM development and review activities covering FY 2011-2019 can be found at: **https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/publications-and-reports**

[3] See: **https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx**

[4] WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020, available at: **https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020**

[5] For the latest available snapshot of FDA's response, see FDA COVID-19 Response At-A-Glance Summary, at: **https://www.fda.gov/media/137005/download**

[6] For more information see Coronavirus Treatment Acceleration Program (CTAP), at: **https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap** and The Path Forward: Coronavirus Treatment Acceleration Program, at: **https://www.fda.gov/news-events/fda-voices/path-forward-coronavirus-treatment-acceleration-program**

[7] See COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders**

[8] EUA information, and list of current EUAs is available at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization**

[9] Also see A Closer Look at the FDA's Center for Devices and Radiological Health's Unprecedented Efforts in the COVID-19 Response, at: **https://www.fda.gov/news-events/fda-voices/closer-look-fdas-center-devices-and-radiological-healths-unprecedented-efforts-covid-19-response**

[10] Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices, available at: **https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices**

[11] Also see Coronavirus (COVID-19) Update: FDA takes further steps to help mitigate supply interruptions of food and medical products, at: **https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-further-steps-help-mitigate-supply-interruptions-food-and**

[12] See FDA Provides Flexibility to the Food Industry to Support Food Supply Chain and Meet Consumer Demand During COVID-19, at: **https://www.fda.gov/news-events/fda-voices/fda-provides-flexibility-food-industry-support-food-supply-chain-and-meet-consumer-demand-during**

[13] See USDA, FDA Strengthen U.S. Food Supply Chain Protections, at: **https://www.fda.gov/news-events/press-announcements/usda-fda-strengthen-us-food-supply-chain-protections**

[14] Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, available (archived) at: **https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/** (cited: March 23, 2021)

[15] The list, and additional information is available on the page Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs at: **https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs**

[16] Also see FDA Protects Patients and Consumers from Fraud During COVID-19, at: **https://www.fda.gov/news-events/fda-voices/fda-protects-patients-and-consumers-fraud-during-covid-19**

[17] See Fraudulent Coronavirus Disease 2019 (COVID-19) Products, at: **https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products**

[18] Also see: FDA updates on hand sanitizers consumers should not use, at: **https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use**

[19] Also see Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection, at: **https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-new-tool-aid-development-and-evaluation-diagnostic-tests**

[20] For more information, see Cellular signaling and immune correlates for SARS-CoV-2 infection, at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/cellular-signaling-and-immune-correlates-sars-cov-2-infection**

[21] For more information, see FDA and global partners to analyze coronavirus samples, at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/fda-and-global-partners-analyze-coronavirus-samples**

[22] Investigating Decontamination and Reuse of Respirators in Public Health Emergencies, available at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies**

[23] See Decontamination Systems for Personal Protective Equipment EUAs, at: **https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas**

[24] For more information, see Innovation to Respond to COVID-19, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/innovation-respond-covid-19**

[25] See 3D Printing in FDA's Rapid Response to COVID-19, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/3d-printing-fdas-rapid-response-covid-19**

[26] For more information about TTFED, see: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua#taskforce**

[27] For more information, visit **www.fda.gov/coronavirus**

[28] FDA press announcements are available at: **https://www.fda.gov/news-events/fda-newsroom/press-announcements**

[29] Where available, select speeches by FDA officials are posted at: **https://www.fda.gov/news-events/speeches-fda-officials**

[30] Consumer Updates, including COVID-19 topics, are available at: **https://www.fda.gov/consumers/consumer-updates**

[31] FDA's COVID-19 video playlist is available on YouTube at: **https://www.youtube.com/playlist?list=PLey4Qe-Uxcxa3152uA5wSC6XRsOK_-9_x**

[32] FDA Voices, including COVID-19 topics, are available at: **https://www.fda.gov/news-events/fda-newsroom/fda-voices**

[33] A list of FDA interactive media accounts is available at: **https://www.fda.gov/news-events/interactive-media**

[34] To subscribe to a variety of FDA email updates, including MCMi updates, visit: **https://public.govdelivery.com/accounts/USFDA/subscriber/new**

[35] FDA Insight podcasts are available on various podcast apps, and at: **https://www.fda.gov/news-events/fda-newsroom/fda-insight**

[36] See COVID-19 Frequently Asked Questions, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions**

[37] See Multilingual COVID-19 Resources, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/multilingual-covid-19-resources**

[38] Previous issues of the MCMi email update—one of the two sent weekly during the response—are available at: **https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-newsletters**

[39] This toolkit, and other resources for health professionals, is available at: **https://www.fda.gov/health-professionals/coronavirus-disease-2019-covid-19-resources-health-professionals#patient**

[40] Webinars in this series were held in FY 2020 starting March 25, 2020 weekly through September. Materials from previous events are available at: **https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-coronavirus-covid-19-test-development-and-validation-10142020-10142020**

[41] Webinars in this series were held in FY 2020 starting June 9, 2020 every two weeks through September. Materials from previous events are available at: **https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-respirators-and-other-personal-protective-equipment-ppe-health-care-personnel-use**

[42] For more information, see Coronavirus (COVID-19) and Medical Devices, at: **https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices**

[43] More information is available at: Drugs@FDA: **https://www.accessdata.fda.gov/scripts/cder/daf/**, Biologics Products & Establishments: **https://www.fda.gov/vaccines-blood-biologics/biologics-products-establishments**, and Medical Device Databases: **https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases**

[44] For additional information, see the FDA news release at: **https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health**

[45] For additional information, see the FDA news release at: **https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigens**

[46] Also see from HHS: BARDA, Chembio Diagnostics Partnership Results in FDA-Cleared Diagnostic Test for Zika, at: **https://www.medicalcountermeasures.gov/newsroom/2020/chembiozikafda/**

[47] For more information, see Zika Virus Response Updates from FDA, Medical Products (Vaccines, Therapeutics, Diagnostics) at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#medical**

[48] Also see, from HHS: New Pandemic Influenza Vaccine Uses Next Generation Technology to Strengthen Health Security, at: **https://www.phe.gov/ASPRBlog/pages/BlogArticlePage.aspx?PostID=372**

[49] For more information, see FDA approves new drug to treat influenza, available at: **https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treat-influenza**

[50] For updated information about MCM approvals after the FY 2020 reporting period, see MCMi News and Events at: **https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-news-and-events**

[51] FDA. Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles: Guidance for Government Public Health and Emergency Response Stakeholders. April 2019. **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/extending-expiration-dates-doxycycline-tablets-and-capsules-strategic-stockpiles**

[52] For more information, see Expiration date extensions of certain lots of doxycycline hyclate capsules at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-date-extensions-certain-lots-doxycycline-hyclate-capsules**

[53] Additional information is available in the HHS memo, State Antiviral Drug Stockpile, available at: **https://www.fda.gov/media/135460/download**

[54] For the latest updates on expiry dating extensions for chemical nerve agent auto-injectors, see FDA alerts health care providers and emergency responders of expiration date extensions of certain auto-injectors manufactured by Meridian Medical Technologies at: **https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-providers-and-emergency-responders-expiration-date-extensions-certain-auto**

[55] For more information applicable to IVD pre-EUAs, see How to Submit a Pre-EUA for *In vitro* Diagnostics to FDA at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda**

[56] For more information, see NIH Clinical trial of investigational Ebola treatments begins in the Democratic Republic of the Congo at: **https://www.nih.gov/news-events/news-releases/clinical-trial-investigational-ebola-treatments-begins-democratic-republic-congo**

[57] For more information, see Independent Monitoring Board Recommends Early Termination of Ebola Therapeutics Trial in DRC Because of Favorable Results with Two of Four Candidates at: **https://www.niaid.nih.gov/news-events/independent-monitoring-board-recommends-early-termination-ebola-therapeutics-trial-drc**

[58] See the FDA web page FDA Zika virus reference panel for molecular-based diagnostic devices supports product testing for Emergency Use Authorization and 510(k) submissions at: **https://www.fda.gov/vaccines-blood-biologics/science-research-biologics/fda-zika-virus-reference-panel-molecular-based-diagnostic-devices-supports-product-testing-emergency** and A Zika Reference Panel for Molecular-Based Diagnostic Devices as a US Food and Drug Administration Response Tool to a Public Health Emergency in The Journal of Molecular Diagnostics at: **https://doi.org/10.1016/j.jmoldx.2019.06.004**

[59] Also see FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data, at: **https://www.fda.gov/medical-devices/database-reference-grade-microbial-sequences-fda-argos/fda-argos-sars-cov-2-reference-grade-sequence-data**

[60] In previous reports, accomplishments of this team were listed under Warfighter Action Team. The name was updated in FY 2019 to better reflect FDA/DoD collaborations under PL 115-92, enacted in December 2017, and the subsequent FDA/DoD Memorandum of Understanding, signed in November 2018, available at: **https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001**

[61] A list of COVID-19-related guidance documents for industry, FDA staff, and other stakeholders is available at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders**

[62] See for example, Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA (Prescription Drug User Fee Act) Products (December 2017) available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products-guidance-industry** and Requests for Feedback on Medical Device Submissions: The Q-Submission Program (May 2019) available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program**

[63] For more information on Special Protocol Assessments see Guidance for Industry – Special Protocol Assessment (April 2018) available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-protocol-assessment-guidance-industry**

[64] Available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-public-health-emergency-general-considerations-pre-ind-meeting-requests-covid-19-related**

[65] For more information on the Interactive Review Process see Types of Communication During the Review of Medical Device Submissions - Guidance for Industry and FDA Staff available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/types-communication-during-review-medical-device-submissions**

[66] Available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-questions-and**

[67] Available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices**

[68] See Availability of Regulatory Management Plans at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/availability-regulatory-management-plans**

[69] A list of MCM-related events by year is available in the MCMi Events Archive: **https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-events-archive**

[70] Where available, MCM-related legal and policy presentations given by FDA staff can be found at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-legal-and-policy-presentations-publications-and-qas** and MCMi regulatory science presentations can be found at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/mcmi-regulatory-science-presentations**

[71] For more information, see Implementation of the National Biodefense Strategy, published in September 2020 by HHS, at: **https://www.phe.gov/Preparedness/biodefense-strategy/2019-report/Pages/default.aspx**

[72] For more information, see Information for Laboratories Implementing IVD Tests Under EUA at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua**

[73] Information for patients and health care providers about this program was available in 2020 from The Mayo Clinic at: **https://www.uscovidplasma.org/**

[74] See Donate COVID-19 Plasma, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma**

[75] Data as of October 5, 2020, posted publicly by The Mayo Clinic.

[76] See NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options, at: **https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options**, and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), at: **https://www.nih.gov/research-training/medical-research-initiatives/activ**

[77] MOU 225-20-010, available at: **https://www.fda.gov/about-fda/domestic-mous/mou-225-20-010**

[78] MOU 225-20-008, available at: **https://www.fda.gov/about-fda/domestic-mous/mou-225-20-008**

[79] MOU 225-18-027, available at: **https://www.fda.gov/about-fda/domestic-mous/mou-225-18-027**

[80] See Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories, at: **https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas**

[81] Also see Coronavirus (COVID-19) Update: FDA Includes Ventilator Developed by NASA in Ventilator Emergency Use Authorization, at: **https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-includes-ventilator-developed-nasa-ventilator-emergency-use**

[82] See CURE Drug Repurposing Collaboratory, at: **https://c-path.org/programs/cdrc/**

[83] Also see CURE ID App Lets Clinicians Report Novel Uses of Existing Drugs, at: **https://www.fda.gov/drugs/science-and-research-drugs/cure-id-app-lets-clinicians-report-novel-uses-existing-drugs**

[84] Through a growing multisectoral partnership of international organizations, non-governmental stakeholders, and more than 50 countries, GHSA is accelerating efforts to build countries' capacity to prevent, detect, and respond to infectious diseases and achieve the core capacities required by the International Health Regulations (IHR)." HHS. Global Health Security Agenda. **https://www.hhs.gov/about/agencies/oga/global-health-security/agenda/index.html**

[85] For more about JEE efforts, see from HHS, U.S. Health Security National Action Plan: Strengthening Implementation of the International Health Regulations, at: **https://www.phe.gov/Preparedness/international/Pages/JEE.aspx**

[86] For example, CBER-WHO Cooperative Agreement: Supporting Influenza Vaccine Introduction to Low-Middle Income Countries (**https://www.fda.gov/vaccines-blood-biologics/international-activities/cber-who-cooperative-agreement-supporting-influenza-vaccine-introduction-low-middle-income-countries**); for more about CBER's WHO Cooperative Agreements, see: **https://www.fda.gov/vaccines-blood-biologics/who-engagements/who-cooperative-agreements**

[87] Follow MCMi on Twitter at: **https://twitter.com/FDA_MCMi**

[88] MOU Concerning Coordination with FDA Regarding DoD Medical Product Development and Assessment (MOU 225-19-01), available at: **https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001**

[89] Also see FDA and DoD formalize collaboration to advance medical products in support of American military personnel, available at: **https://www.fda.gov/news-events/press-announcements/fda-and-dod-formalize-collaboration-advance-medical-products-support-american-military-personnel**

[90] Also see FDA/DoD Collaborations at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-dod-collaborations**

[91] The final guidance is available at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-development-dried-plasma-products-intended-transfusion**

[92] For example, pharmacokinetic modeling was the basis for pediatric labeling of the monoclonal antibody raxibacumab, approved in 2012 to treat inhalational anthrax, in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate. Label information is available at:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125349s000lbl.pdf

[93] Intramural FDA MCM regulatory science is funded through a competitive challenge grant process. Extramural MCM regulatory science is funded primarily through a Broad Agency Announcement (BAA) (Food and Drug Administration Broad Agency Announcement for the Advanced Research and Development of Regulatory Science). More information is available at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/intramural-research** and **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/extramural-research**

[94] A list of tools is available at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/regulatory-science-research-tools**

[95] For more information, see Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection, at: **https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-new-tool-aid-development-and-evaluation-diagnostic-tests**

[96] Also see the EUA letter of authorization at: **https://www.fda.gov/media/136529/download**

[97] For more information about this project, see Investigating Decontamination and Reuse of Respirators in Public Health Emergencies, available at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies**

[98] See Regulatory Science Research Tools, at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/regulatory-science-research-tools**

[99] Also see SARS-CoV-2 Reference Panel Comparative Data at: **https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data**

[100] For more information see FDA Sentinel System's Coronavirus (COVID-19) Activities, at: **http://www.sentinelinitiative.org/assessments/fda-sentinel-systems-coronavirus-covid-19-activities**

[101] The Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) collaborative is a multi-agency/stakeholder network consisting of FDA, CDC, NIH, Office of the National Coordinator for Health Information Technology (ONC), CMS, VA, IVD manufacturers, electronic health record vendors, laboratories, College of American Pathologists, standards developers, Pew Charitable Trusts, National Evaluation System for health care Technology, and academia: **https://aspe.hhs.gov/shield-standardization-lab-data-enhance-patient-centered-outcomes-research-and-value-based-care**

[102] The COVID-19 Evidence Accelerator is an initiative launched by the Reagan-Udall Foundation for the FDA, in collaboration with Friends of Cancer Research, to provide a unique venue for major data organizations, government and academic researchers, and health systems to gather and design quick-turn-around queries and share their results. The project includes a Diagnostics Evidence Accelerator and a Therapeutics Evidence Accelerator. For more information, see: **https://evidenceaccelerator.org/**

[103] For more information, see FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data, at: **https://www.fda.gov/medical-devices/database-reference-grade-microbial-sequences-fda-argos/fda-argos-sars-cov-2-reference-grade-sequence-data**

[104] Also see FDA Zika virus reference panel for molecular-based diagnostic devices supports product testing for Emergency Use Authorization and 510(k) submissions, at: **https://www.fda.gov/vaccines-blood-biologics/science-research-biologics/fda-zika-virus-reference-panel-molecular-based-diagnostic-devices-supports-product-testing-emergency**

[105] FDA awarded this contract in FY 2020. For more information, see FDA and global partners to analyze coronavirus samples, at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/fda-and-global-partners-analyze-coronavirus-samples**

[106] FDA awarded this contract in FY 2020. For more information see Cellular signaling and immune correlates for SARS-CoV-2 infection, at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/cellular-signaling-and-immune-correlates-sars-cov-2-infection**

[107] FDA began distribution of the FDA SARS-CoV-2 Reference Panel in May 2020. For more information, see SARS-CoV-2 Reference Panel Comparative Data at: **https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data**

[108] These findings are important because they suggest the vaccine could both protect recipients and reduce transmission—even when virus strains emerge with differing envelope proteins, a type of change, that when it occurs, can make existing influenza vaccines less effective. Also see, in *Vaccine*: Reduction of influenza virus transmission from mice immunized against conserved viral antigens is influenced by route of immunization and choice of vaccine antigen, available at: **https://doi.org/10.1016/j.vaccine.2018.06.051**

[109] For additional information, see Influenza candidate vaccine viruses improved by amino acid substitution in hemagglutinin, at: **https://www.fda.gov/vaccines-blood-biologics/influenza-candidate-vaccine-viruses-improved-amino-acid-substitution-hemagglutinin**

[110] For additional information, see from HHS, Tick-Borne Disease Working Group, at: **https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html**

[111] Learn more about Agency-wide support for advanced manufacturing in Investing in Advanced Manufacturing to Support Public Health Preparedness, at: **https://www.fda.gov/news-events/fda-voices/investing-advanced-manufacturing-support-public-health-preparedness**

[112] For more information, see 3D Printing in FDA's Rapid Response to COVID-19, at: **https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/3d-printing-fdas-rapid-response-covid-19**

[113] Meeting materials including a recording, printable slides, and transcript, are available at: **https://www.fda.gov/medical-devices/news-events-medical-devices/virtual-town-hall-3d-printed-swabs-05152020-05152020**

[114] For more information about this exercise, see from FEMA, Shaken Fury 2019, at: **https://www.fema.gov/shaken-fury-2019**

[115] Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, available (archived) at: **https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/**

[116] For more information see Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, at: **https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs**

[117] For more information on PAHPAIA, see MCM-Related Counterterrorism Legislation at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation**

[118] When final, this guidance will represent the Agency's current thinking on this subject. The draft guidance is available at: **https://www.fda.gov/media/110193/download**

[119] See Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2020 (84 FR 51597, September 30, 2019). **https://www.federalregister.gov/documents/2019/09/30/2019-21198/fee-for-using-a-material-threat-medical-countermeasure-priority-review-voucher-in-fiscal-year-2020**

[120] Material threat MCM PRVs issued are listed on FDA website at: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv**

[121] The Notice of Proposed Rule Making can be found at: **https://www.federalregister.gov/documents/2018/11/15/2018-24822/institutional-review-board-waiver-or-alteration-of-informed-consent-for-minimal-risk-clinical**. For more information, see FDA's guidance IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects at: **https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk**

[122] Also see, in the Federal Register, Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, at: **https://www.federalregister.gov/documents/2020/03/25/2020-06222/process-for-making-available-guidance-documents-related-to-coronavirus-disease-2019**

[123] Also see, in the Federal Register, Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, at: **https://www.federalregister.gov/documents/2020/03/25/2020-06222/process-for-making-available-guidance-documents-related-to-coronavirus-disease-2019**

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