U.S. FOOD & DRUG ADMINISTRATION

FY 2025

MCM Program Update

FDA MEDICAL COUNTERMEASURES

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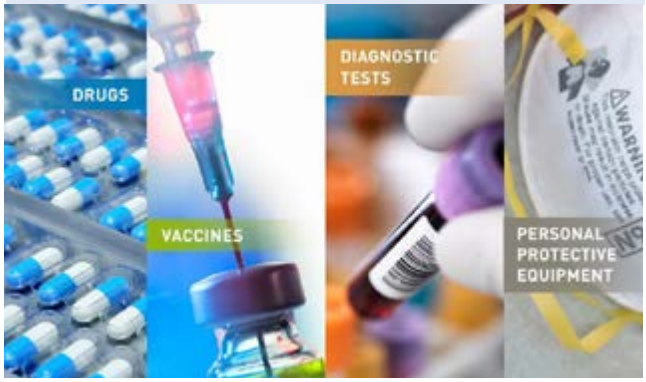
Background

The U.S. Food and Drug Administration plays a critical role in protecting the U.S. from the health impacts of chemical, biological, radiological, and nuclear (CBRN) threats, including emerging infectious diseases, such as New World screwworm, pandemic flu, COVID-19, and mpox. The FDA facilitates timely development of and access to safe and effective **medical countermeasures** (MCMs) to counter such threats.

What are medical countermeasures?[1]

Medical countermeasures, or MCMs, are FDA-regulated products, including biological products, drugs, and medical devices, that may be used to diagnose, prevent, or treat diseases or conditions associated with CBRN threat agents, including emerging infectious diseases.



FDA[2] facilitates preparedness and response efforts for CBRN threats by prioritizing implementation of **legal authorities** that foster **MCM** development and availability. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (**PAHPRA**)[3] requires the FDA to issue an annual report detailing specific MCM activities. This report responds to that requirement for fiscal year (FY) 2025 (October 1, 2024 – September 30, 2025).[4] Codified in section 565(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act (**21 USC § 360bbb-4**), the FDA is required to report specific MCM-related activities each year.

This FY 2025 MCM report focuses on the statutory reporting requirements with links added to the FDA's web information — updated throughout the year — detailing the FDA's comprehensive activities to advance the development and availability of MCMs to protect against CBRN threats, including emerging infectious diseases. The scope of the FY 2025 report is limited to new, innovative MCMs and supplements for new MCM indications, particularly those for which development is funded by U.S. government agencies. It excludes the many supplements or amendments for minor changes, such as those related to MCM chemistry, labeling and storage, and products developed specifically for seasonal flu, respiratory syncytial virus, antimicrobial resistance and others, all of which remain integral to preparedness and response.

FDA's key preparedness and response activities are highlighted in ***Box 1***.

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[1] Medical countermeasures (MCMs) include qualified countermeasures as defined in section 319F–1(a)(2)(A) of the Public Health Service Act (PHS Act) (42 U.S.C. § 247d–6a(a)(2)(A)); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 U.S.C. § 247d–6d(i)(7)); and security countermeasures as defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. § 247d–6b(c)(1)(B)). Some medical products (e.g., sepsis diagnostics) discussed in this report may not meet the statutory definition of MCMs but are included in this report because their development is being supported by MCM-response partners. For purposes of this report, the term "drugs" includes "animal drugs" unless specifically delineated as "human drugs."

[2] In addition to FDA's medical product Centers, FDA's medical countermeasure (MCM)-related regulatory science portfolio is coordinated in FDA's Office of the Chief Scientist's **Office of Regulatory and Emerging Science** (**ORES**) and its public health emergency preparedness and response functions are coordinated by the **Office of Public Health Preparedness and Response** (**OPHPR**).

[3] Public Law (P.L.) 113-5, 127 Stat. 161 (2014).

[4] Detailed information on the FDA's MCM development and review activities covering fiscal years (FY) 2011-2024 can be found on the **FDA Medical Countermeasures Publications and Reports** webpage.

Box 1: Key FDA activities to prepare for and respond to public health emergencies by facilitating development of and access to MCMs

Providing feedback on proposals for development and use of MCMs, including clinical trial design, set-up and data collection for studies, and expediting regulatory reviews of marketing submissions and approving[5] those that meet applicable review standards for use during public health emergencies (PHEs), including for use in outbreaks in other countries

Working with the USG partners and international partners to facilitate access, if necessary, to MCMs that are not approved for the proposed use through an appropriate regulatory mechanism (e.g., clinical trial participation, expanded access,[6] and **emergency use authorities including Emergency Use Authorizations (EUAs)**)[7], including participating in USG responses to outbreaks in other countries, such as Ebola, Marburg, and Mpox outbreaks in Africa during FY 2025

Addressing issues related to import and export of MCMs for emergency use and stockpiling

Working with USG partners to improve clinical trial infrastructure and the ability to **monitor and assess MCMs** used during PHEs

Advancing FDA capacities to monitor MCM **supply chains** to: identify product shortages and support adequate supplies of MCMs through such efforts as extending the shelf life of certain stockpiled MCMs; prevent the distribution of misbranded, counterfeit, adulterated, or unapproved products; and support inter-agency collaboration on efforts to support and strengthen MCM supply chain resiliency

Identifying and catalyzing the resolution of regulatory science challenges and sustaining the **MCM Regulatory Science Program** to create tools, standards, and approaches to help develop and assess MCM safety, efficacy, quality, and performance

Encouraging approaches to produce MCMs through **advanced manufacturing technologies**

Identifying and catalyzing the resolution of regulatory policy challenges and ensuring that the FDA **legal, regulatory, and policy framework** adequately supports MCM development availability, enabling preparedness and response activities

Sustaining the **professional development program** to ensure that FDA personnel maintain the requisite skills and abilities to support the FDA's MCM mission

Advancing global health security through provision of technical expertise and global leadership in regulatory harmonization efforts

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[5] For purposes of this document, the term "approve" is used generally to refer to products that are FDA approved, licensed, cleared or granted De Novo authorization under sections 505, 510(k), 512, 513(f)(2), 515, or section 351 of the PHS Act or conditionally approved under section 571 of the FD&C Act. When referring specifically to medical devices marketed under a premarket approval application, 510(k) premarket notification, or De Novo authorization, the term "approved," "cleared" or "granted" may be used, as applicable. The term "approve" does not include authorization under section 564 of the FD&C Act.

[6] Section 561 of the FD&C Act (21 U.S.C. § 360bbb).

[7] Section 564 of the FD&C Act (21 U.S.C. §§ 360bbb-3) for EUAs and section 564A of the FD&C Act (21 U.S.C. §§ 360bbb-3a) for MCMs that are FDA-approved for the emergency use but may necessitate certain flexibilities.

Response Coordination

In addition to coordinating with partners on outbreaks of Ebola, Marburg, and mpox in Africa and ongoing efforts to mitigate impacts of Highly Pathogenic Avian Influenza (HPAI) outbreaks in the U.S., FDA worked to advance the development, regulatory review, and availability of MCMs for New World screwworm (NWS) in animals. FDA is working with regulated industry, government partners, including through the U.S. One Health Coordination Unit, as well as international and state animal health officials to address the **threat of NWS infestation** in the U.S.

On August 18, 2025, the Secretary of Health and Human Services determined that "there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*)" and declared that "circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent New World screwworm myiasis in animals," thus enabling FDA to issue EUAs to address the emerging threat.[8]

No EUAs for NWS animal drugs were issued in FY 2025. For updated EUA information, see FDA's **NWS website**.

New World screwworm larvae. Photo credit: CDC

FY 2025 Resources for MCM Activities

The FDA obligated an estimated $183.9 million in fiscal year (FY) 2025 to support medical countermeasure (MCM) activities to prepare for and respond to chemical, biological, radiological, or nuclear (CBRN) threats, COVID-19, and pandemic flu (***Table 1***). These resources comprised a combination of base funding and no-year funding. This funding supported 600 full-time equivalents (FTEs).

Table 1: FY 2025 resources obligated to MCM activities

Resource	Enacted (dollars in millions)	FY 25 FTE Enacted
CBRN Base Funding	$141.3	510
Pandemic Flu Base Funding	$42.6	90
Total	**$183.9**	**600**

[8] Issued pursuant to Section 564 of the FD&C Act.

Medical Countermeasure Approvals

During fiscal year (FY) 2025, the FDA continued to review marketing submissions and approve[9] safe and effective MCMs against CBRN threats, including emerging infectious diseases and New World screwworm. MCM approvals are listed in ***Appendix 1*** and ***Appendix 2.*** Here are a few notable highlights from FY 2025, based on novelty and impact to public health preparedness and response:

Threats to US Military Forces

- On December 19, 2024, FDA granted approval for Humacyte's acellular tissue engineered vessel (SYMVESS). This is an important product to the warfighter as it is a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

Chemical Threats

- In October 2024, FDA approved pyridostigmine bromide extended-release tablets for pretreatment against the lethal effects of soman nerve agent poisoning in adults.

COVID-19

- FDA approved three COVID-19 vaccines for **2025-2026 formulations** for certain populations.

- FDA cleared 25 IVD tests for COVID-19, including molecular and antigen tests for detection of SARS-CoV-2 specifically or in combination with other common respiratory viruses, such as influenza A, influenza B, and Respiratory Syncytial Virus (RSV).
- In October 2024, FDA granted de novo marketing authorization for an over-the-counter test that can detect COVID-19 and flu (Healgen Rapid Check COVID-19/Flu A&B Antigen Test). Validation data for the test was gathered through the **Independent Test Assessment Program (ITAP)**, a National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Tech program in collaboration with the FDA. This authorization along with the associated special controls facilitated six additional IVD 510(k) clear-ances in FY 2025 for multi-analyte OTC tests. Throughout FY 2025, FDA continued collabo-rations with U.S. government (USG) partners and academia to assess at-home COVID-19/Flu combination antigen IVD test performance.

- In FY 2025, FDA also cleared one serology test for COVID-19 for detection of total antibodies to SARS-CoV-2.

New World Screwworm (NWS)

- On September 30, 2025, the FDA **conditionally approved** Dectomax-CA1 (doramectin injection) injectable solution for use in cattle to prevent and treat NWS larval infections, and prevention of NWS reinfestation for 21 days.

Pandemic Flu Preparedness

- In May 2025, FDA approved a supplemental application that expanded use of **Xofluza (baloxavir marboxil)**, indicated for treatment of acute uncomplicated influenza in certain individuals, to include post-exposure prophylaxis of influenza.

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[9] See footnote 5.

Sepsis[10]

- FDA cleared three IVD tests as aids in the early detection of sepsis in high-risk patients presenting to intensive care units or emergency departments.

Tularemia

- In September 2025, FDA cleared use of the *Francisella tularensis* Real-time PCR Assay for the qualitative detection of chromosomal DNA sequences from *Francisella tularensis* in whole blood EDTA, pleural fluid, and bacterial culture isolates grown on agar from individuals suspected of having tularemia.

Additional Marketing Submissions in Progress

Twenty-six additional marketing submissions for new MCMs or new MCM indications remained under FDA review at the end of the reporting period. This FY 2025 report is the first one to include animal drug products into this accounting of pending submissions. While the FDA is working toward meeting the goal date for a decision for each of these submissions, the FDA is generally prohibited from disclosing any determinations regarding the filing or approvability of any marketing submission, as well as earlier-stage interactions, for a medical product under applicable statutory and regulatory provisions unless the submission is approved or other grounds for disclosure apply.

Enabling Access To MCMs Under FDA's Emergency Use Authorities

In fiscal year (FY) 2025, the FDA continued to work with U.S. government (USG) partners and product sponsors[11] to provide support for enhanced development and potential availability of candidate medical countermeasures (MCMs).[12] When circumstances warrant and with availability of appropriate data for FDA review, the FDA has a number of mechanisms to facilitate access to certain candidate MCMs that do not have approved indications for the intended use. One way the FDA does this is by issuing emergency use authorizations (EUAs). The EUA authority[13] allows the 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 chemical, biological, radiological, or nuclear (CBRN) agents, or, for the Department of War (DOW) 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.[14]

Lists of **current EUAs** are published on the FDA website. The FDA, to the extent appropriate and permitted by law, publicly posts reviews of scientific

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[10] Sepsis can be caused by any infection or injury that may originate from a chemical, biological, radiological, or nuclear (CBRN) threat or any other source and is a national security priority.

[11] For purposes of this document, the term "sponsor" is used synonymously with the term "applicant," referring to submitters of applications.

[12] This support includes numerous activities, including availability of pre-investigational new drug application (IND) and pre-investigational new animal drug (INAD) 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.

[13] Section 564 of the FD&C Act (21 U.S.C. § 360bbb-3).

[14] The Project BioShield Act of 2004 (P.L. 108-276) amended section 564 to 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 (P.L. 114-255), P.L. 115-92 in 2017, and section 2504 of the Consolidated Appropriations Act of 2023 (P.L. 117-328).

data and information supporting the issuance, revision or revocation of EUAs. Similarly, data and information supporting EUA issuance for in vitro diagnostics (IVDs) is included in the Instructions for Use or EUA Summary documents **published** for every **IVD EUA**. FDA also posts **revoked and terminated EUAs**.

While there was a substantial number of meetings with EUA sponsors regarding pre-EUA and EUA submissions for a variety of CBRN threats, including those for New World screwworm, there was only one new EUA for a COVID-19 IVD issued in FY 2025.

COVID-19

FDA continued to work with sponsors to transition MCMs to traditional regulatory pathways, with only one new EUA issuance for the Metrix COVID/Flu Test.

Table 2: COVID-19 EUA Summary

Product type	New COVID-19 EUAs issued in FY 2025	Total COVID-19 EUAs issued since 2020*
IVDs	1	554
Drugs and biological therapeutics	0	22
Vaccines	0	4
Other devices**	0	63
Total	**1**	**643**

**This total includes EUAs that are no longer active (i.e., EUAs that have been revoked or terminated).*

***Multiple devices were authorized for use under a single "umbrella" EUA in some cases, including certain tests, personal protective equipment, and ventilators/accessories. Each umbrella EUA is counted here as a single EUA.*

EUA Revisions

The FDA also modified or amended EUAs as appropriate, including revisions to EUA fact sheets and instructions for use.[15]

- Multiple revisions were made to COVID-19 therapeutic and device EUAs in FY 2025 — a substantial and ongoing effort. The latest information is available on the **FDA website**. Of note, FDA:
  - Updated the healthcare provider fact sheet for Pemgarda three times to include information about the drug's activity against circulating virus variants; and
  - Revised 31 COVID-19 IVD EUAs. Four of these merited re-issuance of EUA letter of Authorization: (1) two to update ownership of the authorized devices; (2) one to remove one of the authorized self-collection devices; and (3) one to remove the presumptive negative claim based on results of additional prospective clinical data. Twenty of the revisions were related to extending the shelf life of COVID-19/Flu diagnostic antigen tests, many of which were for over-the-counter (OTC) use. In addition, FDA received one EUA report on test performance submitted as a condition of authorization.
- FDA revised three EUAs for Mpox IVDs.
- FDA revised one EUA for an H7N1 IVD.

EUA Revocations

The FDA may also revoke an individual EUA prior to the termination of its underlying EUA declaration.[16] Information about revoked and terminated EUAs is available on the FDA webpage **Emergency Use Authorization–Archived Information** and published in the Federal Register.

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[15] Section 564(g)(2) of the FD&C Act.

[16] Section 564(g)(2) of the FD&C Act. Examples of circumstances that may make revocation appropriate to protect the public health or safety are described in the FDA Guidance Document: **Emergency Use Authorization of Medical Products and Related Authorities**.

In FY 2025, the FDA revoked:

- Three EUAs for COVID-19 vaccines
- One EUA for COVID-19 convalescent plasma
- Seven EUAs for COVID-19 drugs
- 17 EUAs for COVID-19 diagnostic tests

Expiration Dating Extensions[17]

When appropriate, the FDA helps to ensure adequate supplies of MCMs by extending the expiration date of certain stockpiled MCMs based on review of scientific data. The FDA can use several regulatory mechanisms to extend expiration dates, including issuing or revising EUAs, approving supplemental marketing applications, and using an emergency use authority (section 564A(b) of the FD&C Act). FDA also may express its intent to exercise enforcement discretion regarding unapproved extensions when scientifically supportable.

The FDA continues to review applicable data through the **Shelf-Life Extension Program (SLEP)** to assess whether, if properly stored, certain lots of federally-stockpiled MCM drug products can continue to be held and used for an emergency

response beyond the original labeled expiration date for a period specified by the FDA, to help ensure ready access to these products. The FDA developed a controlled accelerated aging approach, combining computer modeling with laboratory testing of both original and aged products to accurately predict the long-term stability of their active components. This laboratory testing provides high-quality data on the condition of stockpiled products, ensuring they remain viable for deployment when needed. In FY 2025, SLEP testing conducted by the FDA to assess drug stability and quality led to shelf-life extensions for approximately 1,509 lots of federally-held MCM drug products.

The FDA maintains an updated **list of some MCM expiration dating extensions** that are publicly available. FDA provides an updated list of expiration dating extensions for **COVID-19 drugs** and **at-home OTC COVID-19 and OTC COVID-19/flu diagnostic tests**. In the interest of national security, FDA's updates to SLEP participants about applicable extensions of the MCMs that they stockpile generally are not posted publicly.

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[17] FDA can extend the expiration date of medical products in a variety of ways, one of which is under section 564A of the FD&C Act (21 U.S.C. 360bbb-3a). For additional information, see FDA Guidance Document: **Emergency Use Authorization of Medical Products and Related Authorities** and **webpage**.

Regulatory Advice and Guidance

During fiscal year (FY) 2025, the FDA continued to provide regulatory advice and scientific guidance to sponsors of MCMs and our federal partners funding MCM development, to help foster the development and availability of various MCMs. The FDA provides regulatory advice and guidance through a variety of mechanisms including direct engagement with sponsors, issuing **guidance documents**, and holding **advisory committee** meetings and public workshops.

FDA medical product review centers engage with MCM sponsors throughout the product life cycle. The FDA established policies and procedures for conducting formal meetings with product sponsors. Formal meetings[18] are held — as needed — at the request of a product sponsor, 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). When the FDA denies a request for a meeting, the FDA's letter will explain the reason for the denial. Formal meetings may also be rescheduled or canceled as described in FDA guidance.

Types and Numbers of Human Drug and Biologic Product Meetings

Under the Prescription Drug User Fee Act (PDUFA), the FDA Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) categorize **formal meetings** with product sponsors of new drug applications and biologics license applications as Type A, B, C, and D. In FY 2025, CBER provided written responses or held 16 formal meetings with MCM sponsors and 61 other MCM-related meetings, and CDER provided written responses or held 66 formal meetings (***Table 3***) and 79 other MCM-related meetings.

Table 3: FY 2025 formal meetings between CBER or CDER and MCM sponsors

Meeting Type	CBER	CDER
Type A	0	0
Type B	11	31
Type C	5	21
Type D	0	14
Total	**16**	**66**

[18] There are four meeting formats: In person face-to-face, virtual face-to-face, teleconference, and Written Response Only. See FDA Guidance Document, **Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products**.

Types and Numbers of Medical Device Meetings

The FDA Center for Devices and Radiological Health (CDRH) received 83 Pre-Submission (Pre-Sub) and six Submission Issue Request (SIR) meeting requests (related to marketing submissions) for MCM devices in FY 2025. CDRH provided extensive written feedback on the Pre-Subs, and many of these sponsors elected to cancel meetings after receiving this written feedback, as they did not see the need for the originally requested meeting. If the sponsor wanted to further discuss the written Pre-Sub feedback, a Pre-Sub meeting was held. The FDA holds SIR meetings sometimes to discuss deficiencies identified during premarket review of device marketing submissions and to provide clarification of the FDA's questions or to discuss an approach to address complex issues identified. In FY 2025, CDRH provided written feedback for 82 MCM Pre-Subs or SIRs and held 21 Pre-Sub and 5 SIR meetings with MCM sponsors (***Table 4***).

Table 4: FY 2025 meetings between CDRH and MCM sponsors

Meeting Type	CDRH
Pre-Sub	21
SIR meetings	5
Total	**26**

Types and Numbers of Animal Drug Meetings

The Center for Veterinary Medicine (CVM) held between 27 and 47 MCM-related meetings in connection with applications for approval, applications for conditional approval, and requests for emergency use authorization in FY 2025. Because animal drug sponsors often opt for phased review, where available, meetings may occur well in advance of the submission of corresponding applications. As such, some meetings related to submissions in FY 2025 may not be reflected in this chart. As this is the first year in which CVM is reporting, and informal meetings are not routinely recorded, the numbers in ***Table 5*** are presented as a range.

Regulatory Management Plans

In addition, eligible MCM sponsors can request a **Regulatory Management Plan** (RMP), setting forth a process where the terms for interactions between the FDA and the product sponsor can be delineated. The FDA did not receive any written-MCM-related RMP requests in FY 2025.

Table 5: FY 2025 Meetings between CVM and MCM sponsors re: MCMs intended for use against NWS.

Meeting Type	CVM
Formal (e.g. Pre-Sub Conference)	0
Informal	27–47
Total	**27–47**

Action Teams

The FDA engages extensively with its federal partners (e.g., White House, HHS Administration for Strategic Preparedness and Response (ASPR), HHS Biomedical Advanced Research and Development Authority (BARDA) and sister HHS agencies and offices, and Department of War (DOW) often under established federal coordinating structures.[19] The FDA's interagency collaborations include numerous engagements through the Public Health Emergency Medical Countermeasures Enterprise (**PHEMCE**) and with the DOW to ensure FDA resources are appropriately used for review of MCMs targeting the U.S. government's (USG's) highest priority threats.[20] MCM approvals and authorizations during FY 2025 can be attributed to the success of these enhanced engagements year after year.

The FDA provided subject matter expertise and technical assistance through 110-120 standing interagency and HHS/PHEMCE and DOW-specific committees and working groups[21] that develop MCM requirements, plans, priorities, and policies and conduct program oversight and integration. These standing committees and working groups met as needed to address a range of topics across the full spectrum of activities associated with MCMs including threat assessment, requirements setting, product development, proposal reviews, procurement, stockpiling, utilization, and monitoring and assessment of MCMs after they have been dispensed or administered.

FDA/DOW Enhanced Engagements Action Team

The FDA works to facilitate the development, regulatory review and availability of MCMs to support the unique needs of American military personnel,

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[19] The FDA's national and global health security roles and responsibilities are guided by U.S. and HHS strategic frameworks. See, e.g., National Health Security Strategy, 42 USC 300hh-1, **The National Biodefense Strategy and Implementation Plan**, October 2022.

[20] **PHEMCE high-priority threats**.

[21] **PAHPRA**'s reporting requirements refer to "Action Teams" established under section 565(b)(4) of the FD&C Act, which codified FDA's established multidisciplinary teams 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 highlighted collaborations in this section reflect enhanced engagements that function as "MCM Action Teams" for reporting purposes. Nonetheless, FDA engages in many other standing, enhanced engagements not specifically reported, such as support for PHEMCE Working Groups and other Working Groups focused on MCMs for specific threats, such HHS's Highly Pathogenic Avian Influenza Working Group and the U.S. One Health Coordination Unit, currently focused on the New World screwworm.

including under a **joint program**[22] established under Public Law (P.L.)115-92[23] to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel.

Under the framework, DOW develops and maintains a Medical Product Priority List, reflecting the most important and urgent MCMs based on needs and feasibility that require increased engagement. For calendar year 2025, there were originally a total of 23 MCMs identified by DOW on the list, which DOW occasionally updated.

One MCM approval during FY 2025 (SYMVESS) is attributable to enhanced engagements, highlighted above under approvals and listed in ***Appendix 1***.

P.L. 115-92 requires semi-annual review of DOW's listed priorities between DOW and the FDA's three medical product centers and quarterly meetings between DOW and the FDA CBER. In practice, the statutory meetings are held quarterly with MCM experts and executive-level officials from all three medical product centers participating. There are many informal Center-specific meetings and monthly "Action Officer" meetings where MCM experts can troubleshoot DOW priority development challenges. These enhanced engagements undergird the FDA's formal regulatory meetings with DOW performers, ensuring maximally efficient discussions.

For example, FDA CDRH's enhanced engagement for one product can account for reduced Q-submission timelines from 70 days down to 35 and 12 days. For another product multiple rounds of email feedback for non-clinical testing protocols were 7 days or less, and for another one, FDA negotiated and hosted a timely informational Q-submission (on site demonstration) of the product to ensure upcoming submissions were founded in keen understanding of the device design and performance.

Microbial Sequencing and Multiplex In Vitro Diagnostics (IVD) Action Team

This Action Team supports sequence-based diagnostic device development, including multiplex diagnostic devices that test for multiple pathogens simultaneously from a single clinical specimen. Key activities during FY 2025 included:

- Continuing to advance the publicly available database for reference-grade microbial genomic sequences, FDA-ARGOS, through the use of a genome assembly quality assessment tool. In FY 2025, this project added approximately 5,000 sequences to the database. This approach enables a shift from a reactive to a proactive posture for infectious disease outbreak preparedness.

- Continuing to expand the FDA-ARGOS database with a focus of upper respiratory pathogens, including multiple biothreat agents.

- Through an interagency agreement (IAA), FDA is continuing the collaboration with the National Institute of Standards and Technology (NIST) to identify and characterize use cases and validation approaches for next-generation

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[22] The DOW Action Team preceded P.L.115-92; DOW-FDA's current enhanced engagements function under the P.L. 115-92 framework. The FDA and DOW entered into a **Memorandum of Understanding** 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 and building 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.

[23] Dec. 12, 2017 (131 Stat. 2023).

sequencing technology in infectious disease medical devices. In addition, FDA and other USG agencies, including the BARDA and NIST through the IAA, are coordinating efforts on the use of agnostic testing devices in pandemic preparedness.

Acute Radiation Syndrome Action Team

This Action Team supports development of MCMs to combat radiological and nuclear threats. These MCMs improve survival and mitigate or treat injuries from radiological/nuclear (rad/nuc) events and determine exposures in a nuclear detonation. Key activities during FY 2025 included:

- Continuing to engage with (1) the ASPR Blizzard Working Group to provide regulatory updates on the **HHS Radiation Emergency Medical Management (REMM)** guidance and facilitate development of radiation biodosimetry devices; and (2) the ASPR radiological/nuclear MCM Working Group to provide input on the recommendations of rad/nuc MCM portfolio.

- Continuing to interact with USG partners to discuss regulatory challenges on development of rad/nuc MCMs including decorporation therapy for inhaled radionuclides and restoration of immune function after radiation injury.

- Continuing to provide FDA reviewers training including seminars on new nuclear reactor technologies and radiological and nuclear emergency preparedness including potassium iodide (KI) implementation.

- Continuing to support biodosimetry review group activities, including review of certain pre-submissions and pre-EUA submissions relating to radiation biodosimetry devices.

Medical Countermeasure Regulatory Science

The goal of FDA's **MCM Regulatory Science Program** is to develop tools, standards, and approaches to assess MCM safety, efficacy, quality, and performance, and to help translate cutting-edge science and technology into innovative, safe, and effective MCMs, including for specific populations. In FY 2025, the FDA continued to implement the MCM Regulatory Science Program to sustain priority research areas through **intramural** and **extramural** collaborative research, as well as through partnerships with USG agencies, academia, and industry. 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, "**Food and Drug Administration Broad Agency Announcement for the Advanced Research and Development of Regulatory Science**."

To ensure that the MCM Regulatory Science Program is appropriately targeted and coordinated with USG MCM priorities, the FDA coordinates with interagency partners including representatives from the NIH, Centers for Disease Control and Prevention, BARDA, and DOW, to evaluate MCM Regulatory Science Program research proposals for scientific/technical merit, feasibility, and alignment with

PHEMCE priorities.

In addition to the many regulatory science projects described in detail under the "Collaborations through Action Teams" section and referenced in FDA webpages, the following extramural projects warrant highlighting because of their novelty and potential impact to public health preparedness and response:

- Continuing research and model development for pediatric and adult patients toward predicting long-term health effects after COVID-19. This program continues to address residual questions of long-term, chronic health impacts from SARS-CoV-2 infection and inform on the development of standards to identify and treat long-COVID.

- Using experimental tools to study cellular-level signaling following SARS-CoV-2 infection, enabling more robust cross-species comparisons, to better qualify and increase confidence that biomarkers identified in non-human primate (NHP) models translate to human disease. This directly supports FDA/HHS efforts to ensure animal data can reliably inform human outcomes.

- Conducting regulatory science research to establish the feasibility of alternative animal models for MCM research for Botulinum neurotoxin (BoNT). In FY 2025, FDA continued evaluation of a novel (rabbit) model characterization for BoNT. The initial study concluded in 2025 and comprises lethal dose 50% (LD50) studies for BoNT Types A, B, and E. A natural history study of type E was also completed in 2025, and final natural history studies for types A and B will complete in 2026. This work augments current testing methods and reduces reliance on NHP models, for which there are potential challenges with availability.

- Completed studies to characterize a ferret model that can accurately recapitulate physiological responses of human nerve agent exposure, as well as efficacy with MCMs. This effort will provide an alternative to NHPs for evaluating MCM efficacy following nerve agent exposure.

- Using systems biology and machine learning approaches to enable comparison between in vitro and in vivo models and clinical data of host-pathogen responses, enabling enhanced and host-directed MCM screening methods. This approach targets enhanced efficiency of pre-clinical data to support novel MCM development, potentially augmenting existing methods to enhance MCM availability.

- Continuing to work on the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) program which aims to build, implement, and support a comprehensive solution addressing clinical and semantic device interoperability of IVDs across the nation.

- Working with the Clinical Trials Transformation Initiative to develop a comprehensive, standardized approach to assessing the readiness and capacity of U.S. clinical trial sites to generate timely and impactful clinical evidence, particularly during public health emergencies.

In addition to these extramural projects, FDA is working to produce the annual influenza reactivity panel to support manufacturers of FDA-cleared antigen-based influenza detection tests to assess their test reactivity with contemporary influenza strains and in compliance with the special controls included in the Influenza virus antigen detection test system classification regulation (21 C.F.R. § 866.3328).

FDA also supported three intramural research projects totaling $450,000 to advance regulatory science for MCM development, manufacturing, and evaluation in the following categories:

- **Advanced Biomanufacturing Platform Development:** FDA invested in the development and validation of quality control methods for cell-free protein synthesis (CFPS) manufacturing platforms. An Interagency Agreement (IAA) with the U.S. Army Combat Capabilities Development Command – Chemical Biological Center was executed in August 2025 to obtain pilot and commercial-scale cell extracts for

validation of quality control assays. The validated iv-sfGFP assay will support rapid manufacturing of MCMs against chemical threats, including acetylcholinesterase fusion proteins for organophosphorus nerve agents. This work addresses a critical regulatory gap, as no FDA guidance currently defines chemical manufacturing controls (CMC) expectations for CFPS-manufactured products.

- **Molecular Diagnostics for Animal Health Biosecurity:** FDA supported the validation of molecular methods (biosensor, viability qPCR, LAMP assays) to detect African Swine Fever Virus (ASFV) in animal food. Contracts were established with University of Minnesota (for its biosafety level (BSL)-3 facility), Michigan State University (for biosensor development), and BioGX (for commercial assay production). This multi-sector collaboration (government-academia-industry-international) has produced two peer-reviewed publications with two additional manuscripts in preparation. Novel viability testing revealed unexpected thermal stability of ASFV, with implications for decontamination protocols. Field testing in the Philippines demonstrated biosensor capability in real-world conditions.

- **Pandemic Influenza Vaccine Standardization:** FDA supported the development of a recombinant hemagglutinin (HA) expression platform to rapidly produce potency antibody reagents without requiring live virus. Four new pandemic reagents were prepared for H5 and H1 variant viruses, directly supporting BARDA-contracted vaccine manufacturing. This work addresses critical bottlenecks in pandemic preparedness.

Appendix 1: FY 2025 Medical Countermeasure Approvals – Human Drug and Biological Products

Medical Countermeasure	Sponsor	Date of Approval or Change	Indication and/or Change Approved
COVID-19			
Paxlovid	Pfizer, Inc.	November 19, 2024	Updated labeling to add information regarding the presence of nirmatrelvir and ritonavir in breast milk in a human lactation study, which may increase the availability of information relevant to treatment of COVID-19 in pregnancy or the postpartum period.
Paxlovid	Pfizer, Inc.	January 31, 2025	Updated labeling to add dosing recommendations in patients with severe renal impairment including those requiring hemodialysis.
Nuvaxovid	Novavax, Inc.	May 16, 2025	FDA approved the 2025-2026 formulation for individuals 65 years of age and older or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
mNEXSPIKE and **Spikevax**	ModernaTX, Inc.	May 30, 2025	FDA approved MNEXSPIKE for individuals 65 years of age and older or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. FDA also approved supplemental applications for SPIKEVAX on July 9, 2025 and August 27, 2025 to approve the 2025-2026 formulation for individuals 65 years of age and older or 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Comirnaty	Pfizer, Inc.	August 27, 2025	FDA approved two presentations of the 2025-2026 formulation: one for individuals 65 years of age and older or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19 and another for individuals 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Medical Countermeasure	Applicant	Key Dates	Indication and/or Change Approved
Pandemic Flu Preparedness[24]			
Xofluza (baloxavir marboxil) **NDA 210854 NDA 214410**	Genentech Inc.	May 30, 2025	FDA approved an indication for post-exposure prophylaxis (prevention) of influenza and to include a new packet presentation and revised dosing instructions for oral suspension for pediatric patients.
Smallpox/Mpox			
JYNNEOS **Smallpox and Mpox Vaccine, Live, Non-replicating**	Bavarian Nordic A/S Bavarian Nordic Inc.	March 31, 2025	FDA approved a supplement to include a two-vial presentation freeze-dried formulation of JYNNEOS.
Radiological/Nuclear			
Releuko (Filgrastim-ayow subcutaneous or IV)	Kashiv BioSciences, LLC	April 29, 2025	FDA approved a supplement to add an indication for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis and increased survival in patients acutely exposed to myelosuppressive doses of radiation.
Fylnetra (Pegfilgrastim-pbbk subcutaneous)	Kashiv BioSciences, LLC	April 23, 2025	FDA approved a supplement to add indication for increased survival in patients acutely exposed to myelosuppressive doses of radiation.
Chemical Threats			
Pyridostigmine bromide extended-release tablets	Amneal Pharmaceuti-cals LLC	October 4, 2024	Pretreatment against the lethal effects of soman nerve agent poisoning.
Threats to US Military Forces			
SYMVESS (acellular tissue engineered vessel-tyod)	Humacyte	December 19, 2024	FDA approved a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

[24] For the FY 2025 MCM Progress Report, we are not listing approvals for MCMs specific to seasonal flu that are not directly funded or supported by USG development programs.

Appendix 2: FY 2025 Medical Countermeasure Clearances/Grants – Devices

The FDA cleared or granted de novo authorization to 47 diagnostic tests under the product codes listed in the chart below in FY 2025. Additional information about these diagnostic test device clearances and grants of de novo authorization can be found in the FDA Medical Devices Databases, including the 510(k) Premarket Notification Database. To locate records for a particular type of device, search FDA medical device databases (the 510(k) Premarket Notification Database) for the product code associated with that device type, or by going to the link in the Clearances in FY 25 column.

Diagnostic Tests				
Regulation	**Regulation Description**	**Product Code**	**Product Code Name**	**Clearances in FY25**
866.2950	Microbial nucleic acid storage and stabilization device	QBD	Microbial Nucleic Acid Storage and Stabilization Device	K240797 K242820
866.3215	Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis	PRE	RT-QPCR Assay for MRNA Transcript Immune Biomarkers	K241676
866.3215	Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis	PTF	Assay To Measure Pct to Aid in the Risk Assessment of Critically Ill Patients on Their First Day of ICU Admission	K242294
866.3328	Influenza virus antigen detection test systems	PSZ	Devices Detecting Influenza A, B, and C Virus Antigens	K241188 K250398
866.3970	Device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid	QUT	Deformability Cytometry for Sepsis Risk Assessment	K250513
866.3980	Respiratory viral panel multiplex nucleic acid assay	OCC	Respiratory Virus Panel Nucleic Acid Assay System	K242613

866.3980	Respiratory viral panel multiplex nucleic acid assay	OZE	Influenza A and Influenza B Multiplex Nucleic Acid Assay	**K243274** **K243931**
866.3981	Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test	QOF	Multi-Target Respiratory Specimen Nucleic Acid Test Including SARS-COV-2 And Other Microbial Agents	**K241573** **K241652** **K241806** **K242071** **K242353** **K242465** **K242526** **K243400** **K243406** **K243455** **K243544** **K250080** **K250995** **K250996**
866.3981	Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test	QQX	Respiratory Specimen Nucleic Acid SARS-COV-2 Test	**K240867** **K241580** **K242109** **K243396**
866.3982	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings	QVF	Simple Point-Of-Care Device to Directly Detect SARS-COV-2 Viral Targets from Clinical Specimens in Near-Patient Settings	**K243872** **K250273**
866.3982	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings	QWR	Simple Point-Of-Care Device to Detect SAR-COV-2 Nucleic Acid Targets from Clinical Specimens in Near-Patient Settings	**K243346**
866.3983	SARS-CoV-2 serology test	QVP	SARS-COV-2 Serology Test	**K250768**
866.3984	Over-the-counter test to detect SARS-CoV-2 from clinical specimens	QYT	Over-The-Counter COVID-19 Antigen Test	**K241313** **K241915** **K243518** **K251753**
866.3987	Multi-analyte respiratory virus antigen detection test	SCA	Multi-Analyte Respiratory Virus Antigen Detection Test	**DEN240029** **K243256** **K243262** **K243561** **K250377** **K251563** **K251604**

866.4000	Device to detect and identify biothreat microbial agents in human clinical specimens	PRD	Biothreat Microbial Agents Multiplex Nucleic Acid Detection System	**K243822**
866.4000	Device to detect and identify biothreat microbial agents in human clinical specimens	SGA	Biothreat Microbial Agent Nucleic Acid Detection Test	**K252072**
866.4001	A multiplex respiratory panel to detect and identify emerging respiratory pathogen(s) and common respiratory pathogens in human clinical specimens	QDS	MERS-COV And Common Respiratory Pathogens Semi-Quantitative and Quantitative Multiplex Nucleic Acid Detection System	**K243222**

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