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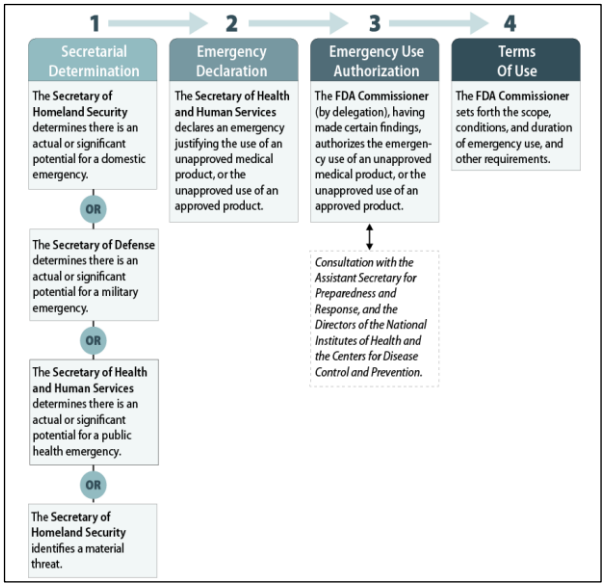
Updated August 13, 2018

Emergency Use Authorization and FDA's Related Authorities

Under most circumstances, drugs, medical devices, and biologics may only be introduced into interstate commerce if they have been approved, cleared, or licensed by the Food and Drug Administration (FDA). Under certain circumstances, however, FDA may permit a medical product to be provided to patients outside the standard regulatory framework. One of these circumstances is if the Secretary of Health and Human Services (HHS) declares, pursuant to §564 of the Federal Food, Drug, and Cosmetic Act (FFDCA), that an emergency or threat exists due to a chemical, biological, radiologic, or nuclear (CBRN) agent, in which case the HHS Secretary may temporarily authorize the emergency use of an *unapproved product* or the *unapproved use of an approved product*. P.L. 115-92, signed into law on December 12, 2017, amended this authority to allow for emergency uses of medical products for threats in addition to CBRN agents, to include agents that may cause or are associated with an imminently life-threatening and specific risk to the United States military. The four-step process required to authorize the emergency use of a medical product—referred to as Emergency Use Authorization (EUA)—is shown in **Figure 1** and described in the following sections.

Figure 1. Steps in Emergency Use Authorization



Source: Developed by CRS based on FFDCA §564.

Secretarial Determination and Declaration

FFDCA §564, established by the Project BioShield Act of 2004 (P.L. 108-276) and amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA, P.L. 113-5) and P.L. 115-92, allows the HHS Secretary to declare that the circumstances exist justifying the emergency use of certain medical products upon one of the following determinations:

- A determination by the Secretary of the Department of Homeland Security (DHS) that there is an actual or significant potential for a domestic emergency involving a heightened risk of attack with one or more CBRN agents;
- A determination by the Secretary of the Department of Defense (DOD) that there is an actual or significant potential for a military emergency involving a heightened risk of attack with either with one or more CBRN agents, or with one or more agents that may cause or are associated with an imminently life-threatening and specific risk to United States military forces;
- A determination by the HHS Secretary that there is an actual or significant potential for a public health emergency that affects or has significant potential to affect national security or the health and security of United States citizens living abroad, and that involves one or more CBRN agents; or
- The identification by the DHS Secretary of a material threat pursuant to Public Health Service Act §319F-2.

The HHS Secretary may fulfill both the determination and declaration functions. Each of the secretarial determination mechanisms have been used as the basis for an EUA, and EUAs have been issued for a variety of uses and products. The emergency declaration must terminate on the earlier of (1) a determination by the HHS Secretary that the emergency no longer exists or (2) a change in the approval status of the product such that the EUA would not be necessary.

Issuance of an EUA

Following the HHS Secretary's declaration, the FDA Commissioner, in consultation with the Assistant Secretary for Preparedness and Response (ASPR) and the Directors of the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), may authorize the emergency use of a specific drug, device, or biologic, by issuing an EUA, provided that certain criteria are met:

- the CBRN agent that is the subject of the EUA can cause a serious of life-threatening disease or condition;
- the product may be effective in diagnosing, treating, or preventing such disease or condition, based on the totality of the available scientific evidence;

- the known and potential benefits of the product outweigh its known and potential risks; and
- there is no adequate, approved, and available alternative to the product.

Conditions of Authorization

FFDCA §564 directs FDA to impose certain required conditions in an EUA and allows for additional discretionary conditions where appropriate. The required conditions vary depending upon whether the EUA is for an *unapproved product* or for an *unapproved use of an approved product*. For an *unapproved product*, the conditions of use must: (1) ensure that health care professionals administering the product receive required information; (2) ensure that individuals to whom the product is administered receive required information; (3) provide for the monitoring and reporting of adverse events associated with the product; and (4) provide for recordkeeping and reporting by the manufacturer. For an *unapproved use of an approved product*, only the first two conditions listed above are required and additional conditions regarding monitoring, reporting, and recordkeeping may be imposed. For both types of EUAs, FDA may waive or limit Good Manufacturing Practice (GMP) requirements (e.g., storage and handling) and prescription requirements.

In general, an EUA will remain in effect for the duration of the emergency declaration made by the HHS Secretary, unless revoked at an earlier date. In either case, the product that was subject to the EUA may continue to be used by a patient who began treatment before revocation or termination, as deemed necessary by the patient's attending physician.

The HHS Secretary (FDA by delegation of authority) must promptly publish in the *Federal Register* a notice of each EUA, along with reasons for issuance, a description of intended use, and any contraindications of the product. The issuance of an EUA authorizes the emergency use of an *unapproved product* or an *unapproved use of an approved product*, but it does not require manufacturers or providers to actually participate in such use.

Emergency Use without an EUA

PAHPRA established new FFDCA §564A, which allows the HHS Secretary (FDA by delegation of authority) to facilitate certain emergency activities involving eligible products, also referred to in FDA guidance as eligible *medical countermeasures* (MCMs). An eligible product or MCM is an *FDA-approved* medical product intended to prevent, diagnose, or treat a disease or condition involving one or more CBRN agents, or a serious or life-threatening disease caused by such product, and that is intended for use when (1) a determination of an actual or significant potential for an emergency has been made by the Secretary of DHS, DOD, or HHS, or (2) a material threat has been identified by the Secretary of DHS. This authority is independent of the EUA authority under FFDCA §564.

Prior to PAHPRA, FDA would often issue an EUA for use of an approved product even if it was intended to be used during an emergency for its approved indication because certain preparedness and response activities (e.g., dispensing without a prescription) otherwise could have violated the FFDCA. Section 564A authorizes FDA to:

- Extend expiration dating of an eligible product for use in a CBRN emergency if the extension is supported by appropriate scientific evaluation;
- Allow deviations from GMP requirements to accommodate emergency response needs;
- Issue emergency use instructions to inform health care providers or individuals to whom the product is being administered about the product's conditions of use; and
- Waive Risk Evaluation and Mitigation Strategies (REMS) requirements for an eligible product based on the same emergency conditions that allow an EUA.

Section 564A also waives the applicability of certain requirements to allow for emergency dispensing without a prescription, provided that such dispensing occurs as permitted by state law in the state in which it is being dispensed, or it is in accordance with an emergency dispensing order issued by FDA.

Products Held for Emergency Use

PAHPRA established new FFDCA §564B, which allows government entities and their agents to preposition or stockpile an unapproved medical product intended for emergency use, provided the product is held and not used until it is approved, cleared, or licensed; authorized for investigational use; or authorized for use under an EUA.

Medical Product Development

FDA is required to take various actions to support the development and review of MCMs, including participation in meetings with applicants and issuance of guidance. Pursuant to P.L. 115-92, upon request from the Secretary of Defense, FDA must take specified actions to expedite the development and review of certain medical products if there is an actual or significant potential for a military emergency and if that medical product would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk. FDA also must meet with DOD and other development partners to discuss the development status of projects that are the highest priorities to DOD (e.g., freeze-dried plasma products and platelet alternatives).

FDA also is required to award a priority review voucher to the sponsor of an approved material threat MCM application that is intended to (1) prevent, or treat harm from a CBRN agent identified as a material threat, or (2) "mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent." The voucher can be used for the priority review of another application.

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IF10745

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