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September 11, 2025

The Honorable Robert F. Kennedy
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201
(Submitted Electronically)

The Honorable Dr. Martin A. Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
(Submitted Electronically)

Re: ***Comments Regarding FDA's Notice of a Proposed Extension of Information Collection Activities Related to Emergency Use Authorization for Medical Products, Docket Number FDA-2025-N-1115***

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter "CPAC Foundation") Center for Regulatory Freedom (hereinafter "CRF") on the U.S. Department of Health and Human Services' (HHS) U.S. Food and Drug Administration's (FDA) notice entitled "Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products," Docket Number FDA-2025-N-1115, published in the Federal Register on July 14, 2025.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals

serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

CRF greatly appreciates the opportunity to comment on the FDA's notice of a proposal to extend, without change, an existing collection of information regarding emergency use authorizations (EUAs) for medical products. This information collection request is especially relevant, as there are between 30 and 50 EUAs currently in effect across all product types in the United States.[1] Moreover, despite the former Secretary of HHS declaring that the COVID-19 public health emergency officially ended on May 11, 2023, there are roughly 10-15 active COVID-19 EUAs for products including therapeutics, vaccines, and diagnostics.[2] Clearly, there is a present abundance (and perhaps overabundance) of EUAs, though prior to the coronavirus pandemic, EUAs were issued very rarely and sparingly. Extending this collection of information and associated information collection activities will simultaneously extend the applicability of standing FDA policy as it relates to EUAs. This policy has failed to reserve EUAs for only the most crucial medical products during the direst health emergencies and instead has allowed certain companies to bypass manufacturing and other requirements, even beyond the conclusion of the pandemic that originally justified the EUA.

Because of this and other reasons to be discussed further in the following comments, CRF does not support the FDA's proposed extension of this collection of information. CRF urges the FDA to realign its policies and practices with the plain meaning of the text of the Federal Food, Drug, and Cosmetics Act (FD&C Act), as amended.

Introduction

The FD&C Act was enacted in 1938 and was initially designed to expand on earlier legislation, applying additional manufacturing standards and other requirements to drugs, food, cosmetics, and therapeutic devices. The FD&C Act has been amended a multitude of times, though it is important to note that, despite its name, it does not direct the Commissioner of the FDA to carry out its provisions, nor issue EUAs. Instead, the FD&C Act repeatedly and explicitly grants this authority to the Secretary of HHS. It was not until the 1980s that Dr. Anthony Fauci, who was, at that time, the Director of the National Institute of Allergy and Infectious Diseases, proposed a new "parallel track" system, allowing an experimental drug to be available to patients, even though that drug was still undergoing clinical trials.[3] Even then, the authority to issue EUAs remained exclusive to the Secretary of HHS, until 2001's infamous War on Terror, wherein

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[1] U.S. Food & Drug Admin., Emergency Use Authorization (Aug. 28, 2025), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[2] Id.

[3] Jonathan Iwry, *FDA Emergency Use Authorization: A Brief History From 9/11 to COVID-19*, 40 Food & Drug L.J. (2021), https://www.fdli.org/2021/09/fda-emergency-use-authorization-a-brief-history-from-9-11-to-covid-19/.

Congress amended the FD&C Act to permit the FDA to authorize formally unapproved products as emergency countermeasures.[4]

Despite this newfound authority, the FDA did not issue very many EUAs in the first sixteen years after Congress amended the FD&C Act, opting to only authorize unapproved products during notable public health crises, such as during the rise of avian flu in 2005, or the H1N1 swine flu pandemic of 2009. However, this restrained issuance of EUAs came to a screeching halt during the COVID-19 pandemic. Unsurprisingly, Dr. Fauci again promoted the use of EUAs during the COVID-19 pandemic, culminating in well over 400 EUAs for personal protective equipment, medical equipment, *in vitro* diagnostic products, drug products, and vaccines.[5] To provide a comparison, the FDA only issued a total of twenty-two EUAs in response to H1N1 in 2009.[6] It is evident that the issuance of EUAs during the coronavirus pandemic was largely abused, leading to numerous safety concerns surrounding EUA products, and this is, in part, due current FDA guidance and its failure to reflect the statutory intent of the FD&C Act.

Problems with Current FDA Guidance

The FDA's most recent formal EUA guidance was finalized in January 2017 and has yet to be formally replaced or updated following the aftermath of the COVID-19 pandemic. This alone is reason enough to revise EUA-related information collections before continuing to perpetuate this policy further. Even though the 2017 guidance does not impose any legal or binding conditions upon any FDA-regulated entities, this policy guidance does reflect the attitudes and official policy positions of the FDA, and thus, reflects how the FDA chooses whether to issue an EUA. One problematic component of this guidance is FDA's explicit encouragement of "alternative regulatory mechanism[s]" as "an appropriate means to provide patients access to an unapproved use of a product,"[7] effectively condoning industry or government sponsors circumventing the FD&C Act. The 2017 guidance also operates outside of the codified scope of the FD&C Act by stating the following:

> "Potential EUA products also include those that may be effective to mitigate a disease or condition caused by an FDA-regulated product (including a product authorized for emergency use under section 564 or an approved product) used to diagnose, treat, or prevent a disease or condition caused by a CBRN agent."[8]

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[4] Jonathan Iwry, *FDA Emergency Use Authorization: A Brief History From 9/11 to COVID-19*, 40 Food & Drug L.J. (2021), https://www.fdli.org/2021/09/fda-emergency-use-authorization-a-brief-history-from-9-11-to-covid-19/.

[5] Id.

[6] Id.

[7] U.S. Food & Drug Admin., *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* (Jan. 12, 2017), https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and.

[8] Id.

Under this guidance, the FDA is authorized to not only issue EUAs to products that "may" be effective in mitigating a disease or condition, but issue EUAs to products designed to treat diseases or conditions caused by other EUA products. This allows the FDA to continuously push unapproved medical products with virtually no consequence, as any problems that may arise from the use of one product authorized for emergency use can simply be treated with yet another product for which the FDA will issue another EUA.

It is important to note that the FDA cannot issue an EUA if there are any "adequate, approved, and available alternative[s] to the candidate product for diagnosing, preventing, or treating the disease or condition."[9] The 2017 guidance expands on this point further, providing criteria for what makes a product "unavailable" or "inadequate." When defining "inadequate" in the context of the FD&C Act, the guidance states that, "A potential alternative product may be considered 'inadequate' if, for example, there are contraindicating data for special circumstances or populations,"[10] citing "individuals with a drug allergy" as an acceptable example. The guidance goes on to state that "if a dosage form of an approved product is inappropriate for use in a special population," such as "a tablet for individuals who cannot swallow pills," that product may be considered "inadequate."[11]

Interestingly, the FD&C Act provides no such definition nor any examples as to what would constitute an "adequate, approved, and available alternative to the product,"[12] and while the definition and corresponding examples of an "inadequate" product in FDA's 2017 guidance reflects the FDA's interpretation of the FD&C Act, this guidance fails to reflect the intent of Congress. By broadening the definition of "inadequate" to encompass products to which certain individuals may be allergic and whether the dosage form of the approved product may be problematic for some individuals, the FDA implicitly increases the frequency with which EUAs are issued. There could be a plethora of approved alternatives available for a product that a sponsor requests be authorized for emergency use, but if those products pose potential health risks for even a small subset of the population, the FDA will grant an EUA, handing a monopoly on that particular medical product market to that industry or government sponsor.

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[9] U.S. Food & Drug Admin., *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* (Jan. 12, 2017), https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and.

[10] Id.

[11] Id.

[12] 21 U.S.C. § 360bbb-3(c)(3).

FD&C Act: Adhering to the Plain Meaning

Rulemaking Authority

Although the FDA currently exercises regulatory oversight over the issuance of EUAs and related rules, this authority is vested in the Secretary of HHS under the FD&C Act. 21 U.S.C. § 360bbb-3(c)(5) reads as follows:

> "The Secretary may issue an authorization under this section with respect to the emergency use of a product only if...the Secretary concludes...that such other criteria as the Secretary may by regulation prescribe are satisfied."[13]

Here, the power to promulgate additional rules and criteria for EUAs is explicitly delegated to the Secretary of HHS. It is within the Secretary's discretion to delegate this authority to the FDA, though there is currently no publicly available formal delegation document explicitly authorizing the FDA to regulate EUAs on the Secretary's behalf. Because the FDA's history of EUA issuance and available policy guidance do not adhere to the plain meaning of the FD&C Act, CRF recommends that the power to put forth criteria, requirements, and standards for EUA issuance be redelegated back to the Secretary of HHS. This reorganization of regulatory responsibilities will allow the Secretary of HHS to dictate the construction of a new EUA framework while ensuring that EUAs will only be issued according to the Secretary's determinations, and at a reasonable rate.

Reporting Adverse Events Associated with EUAs

Another provision of the FD&C Act reemphasizes the Secretary of HHS's authority over specific rules and regulations associated with EUAs. 21 U.S.C. § 360bbb-3(e)(1)(A) authorizes the Secretary of HHS to establish conditions for EUAs "as the Secretary finds necessary or appropriate," including "appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product."[14] This authority is especially important considering the current HHS Secretary's revocation of broad EUAs for COVID-19 vaccines, especially since this revocation followed an increase in available data depicting severe health risks associated with those vaccines.[15]

CRF recommends that, to best implement the provisions and intent of the FD&C Act, the Secretary of HHS promulgate additional rules and regulations concerning monitoring and

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[13] 21 U.S.C. § 360bbb-3(c)(5).
[14] 21 U.S.C. § 360bbb-3(e)(1)(A)(iii).
[15] FDA, FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis (Sept. 11, 2025), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and.

recordkeeping requirements for experimental, unapproved medical products authorized for emergency use. If adverse events associated with the emergency use of a particular product are required to be reported accurately, and the Secretary of HHS institutes a regulatory framework to verify such reports as accurate, the safety of EUAs will be monitored much more effectively, and necessary EUA revocations will occur before a significant portion of the population is treated with an EUA medical product.

Periodic Reviews

The FDA's issuance of EUAs is characterized not only by the abnormal and unprecedented frequency with which they have been issued in recent years, but also by the FDA's inability to thoroughly review past EUAs and determine whether those EUAs are still necessary. The FD&C Act mandates that the Secretary of HHS "periodically review the circumstances and the appropriateness of an authorization,"[16] and though this responsibility, as with all other EUA-related obligations in the FD&C Act, has been delegated to the FDA, the FDA has neglected the directive to go over EUAs "periodically." In fact, there are still active EUAs for medical products that test for the Middle East respiratory virus (MERS-CoV), even though the determination justifying the EUA was made in 2013. The FDA's 2017 guidance states that EUAs "may no longer be needed if that product is later approved by the FDA for the use permitted by the EUA,"[17] meaning that even after more than 10 years of circulating MERS-CoV tests approved for emergency use, the FDA has remained unable to formally approve the products.[18]

CRF recommends that the Secretary of HHS review all EUAs that are currently in effect, prioritizing those that were issued more than five years ago and have yet to be revisited, to assess whether the circumstances warranting such an authorization have changed and why the particular medical product has yet to be formally approved by the FDA. CRF also recommends that the Secretary of HHS expand upon the FD&C Act's use of "periodically" in a rulemaking to establish a consistent recurring timeline of EUA reviews. A consistent schedule of periodic reviews will ensure that EUAs are not used indefinitely to bypass various legislative and regulatory requirements.

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[16] 21 U.S.C. § 360bbb-3(g)(1).

[17] U.S. Food & Drug Admin., *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* (Jan. 12, 2017), https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and.

[18] FDA, Emergency Use Authorization, FDA (Sept. 11, 2025), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#MERS.

Conclusion

Because EUA definitions and policies directly shape the FDA's oversight and enforcement practices, any deviation from the FD&C Act's plain meaning will allow the FDA to give preferential treatment to industry and government sponsors. EUAs have given the FDA the power to unfairly control the medical product marketplace, choosing which sponsors can freely circumvent good manufacturing practices, and for how long. Under the current regulatory framework, the FDA's authority over issuing EUAs is completely uninhibited, and the only pragmatic solution to reconfiguring the EUA process is to reconstruct the FDA's regulatory framework so that the FDA has less total autonomy over EUAs, and the Secretary of HHS regains more of its statutory authority.

CRF opposes the FDA's proposed extension, without change, of this collection of information. CRF urges the FDA to align its EUA policies strictly with the FD&C Act's plain language, reserving EUAs for truly exigent circumstances and ensuring robust, transparent review and periodic reassessment of existing EUAs. Without such realignment, the efficacy and integrity of EUA regulatory authority will continue to be compromised, with potential negative consequences for patient safety and public health policy enforcement.

If you have any questions, do not hesitate to contact me at kmcleroy@conservative.org.

Thank you,

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