Congress of the United States
Washington, DC 20515

September 19, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We are writing to you today with continued concerns involving the systemic problems within the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response and the Center for Tobacco Products (CTP). Recent controversies resulting from failed regulatory frameworks, as you yourself described it,[1] have caused significant marketplace disruptions and regulatory uncertainly. As leader of the FDA, you are responsible for addressing these policy failures and we request details on how you are working to resolve long-standing regulatory issues.

We welcome the recent announcement that FDA would commission an external review of how the regulatory functions within CTP are working.[2] We question, however, the choice to use the Reagan-Udall Foundation to conduct this work. On August 17, the Foundation announced that it has enlisted a former FDA Commissioner, Jane Henney, to lead the CFSAN and the Office of Food Policy and Response review and former FDA Chief of Staff Lauren Silvis to lead the CTP review. The organization was originally established by Congress to "advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.[3]" This body was not designed to support the agency as a strategical and operational partner.[4] Nor was it was ever intended to be an oversight body, which is the role of Congress.

While the announcement notes that they "will work with additional external evaluators who bring relevant expertise from both inside and outside federal government" and that "they will have access to multiple subject matter experts," the announcement does not explain who these experts are, nor does it clarify how industries regulated by these Centers can offer input.[5] It provides some information about the process including stakeholder engagement, and it is our

[1] https://www.fda.gov/news-events/press-announcements/fda-conducting-evaluation-key-agency-activities-strengthen-operations
[2] https://reaganudall.org/news-and-events/coverage/fda-announces-external-review-food-safety-and-tobacco-regulatory-offices
[3] https://www.govinfo.gov/content/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf
[4] https://reaganudall.org/about-us
[5] *Id.*

hope that the review will provide a meaningful opportunity for such engagement and that the resulting reports will be unbiased and objective. Regardless of the findings, you will still be responsible for addressing these issues within FDA and answering to Congress for the decisions being made at FDA under your leadership.

While any review of CFSAN and the Office of Food Policy and Response and CTP should provide some insight into the following issues, separate and apart from the final reports FDA expects to receive within 60 days from the August 17 announcement, we would appreciate your responses to the questions in this letter by October 17, 2022.

Center for Food Safety and Applied Nutrition (CFSAN)

Although Reagan-Udall will not be examining the FDA's regulatory approach to cannabidiol, we hope FDA will examine CFSAN's and the Office of Food Policy and Response handling and the opaque regulatory processes around cannabidiol (CBD). The FDA's regulatory approach to CBD has created unnecessary uncertainty in the marketplace around these products.

The United States currently has a robust but largely unregulated CBD market, which leads to an unsafe marketplace for consumers.[6] Consumer products that contain CBD – such as dietary supplements, food, and beverages – are currently sold across the country under a patchwork of state laws and regulations[7] that have been developed and promulgated in light of FDA's inaction.

This has even led to multiple cases of children purchasing over-the-counter CBD gummies with unsafe levels of delta-8 THC and suffering harm as a result.[8] This is due to the FDA's failure to regulate and enforce statutory standards established by Congress that govern CBD and CBD-derived products.

In the Agriculture Improvement Act of 2018 (Farm Bill), Congress removed hemp-derived CBD from the Controlled Substances Act (CSA), allowing CBD to not be subject to restrictions and oversight as a controlled substance by the Drug Enforcement Agency (DEA). The bill still retained FDA authority to regulate CBD pursuant to the Federal Food, Drug and Cosmetics Act (FFDCA), allowing the FDA to evaluate and study CBD and CBD-derived products that fall under the agency's jurisdiction, including both food and dietary supplements.[9]

Despite Congress removing hemp-derived CBD from the CSA, it still is prohibited from being used as an ingredient in dietary supplements or an additive in any foods and beverages pursuant to Sections 201 and 301 of the FFDCA, unless and until the agency issues rules permitting such uses.

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[6] https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

[7] https://www.forbes.com/health/body/cbd-legalization-by-state/

[8] https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc#:~:text=66%25%20described%20adverse%20events%20after,confusion%2C%20and%20loss%20of%20consciousness.

[9] https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

More frustratingly, following the passage of the 2018 Farm Bill, the FDA claimed they were "committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.[10]" To this end, the agency held a public meeting on May 31, 2019, entitled "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds" and opened a public docket to collect information that would ostensibly lead to and inform the rulemaking process.[11]

However, the agency has yet to create a regulatory roadmap for CBD and CBD-derived products to safely come to market. Instead, the FDA has sent several warning letters to companies making unsubstantiated therapeutic claims[12] and denying companies the opportunity to come to market in a way which is safe and effectively complies with established regulatory standards.[13] Rather than denying new products from coming to market, the FDA must take action and establish a clear set of standards for companies to adhere by, especially since these products are already being sold in states across the nation.

There must be a uniform and established standard that responsible actors can follow that will allow for safe CBD and CBD-derived products to come to market – just as FDA sets standards for all other CFSAN-regulated products. It was disappointing to see in a recent June meeting by the FDA scientific advisory board, just weeks after you testified in front of Congress that FDA cannot "keep trying to do the same thing over and over" with regard to CBD,[14] the panel again leaned on the lack of scientific data[15] in CBD research as the sole reason for the FDA's inaction.

Congress recently passed the Medical Marijuana and Cannabidiol Research Expansion Act which will allow for additional research by creating a more streamlined process and removing FDA barriers. While the FDA inaction in the interim is unacceptable, it is our hope that this will expedite the generation of data and a lawful and safe interstate CBD marketplace.

We request that you answer the following questions:

1. In addition to the public activities noted in this letter, please describe what the agency has done since Congress legalized CBD in 2018 to gather more scientific data and research into CBD?

2. Please provide the specific scientific questions that FDA has posed to NIH, CDC, or to other federal agencies, or academic research institutions engaged in CBD research that it

[10] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys
[11] https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds
[12] https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products
[13] https://hempindustrydaily.com/wp-content/uploads/2021/08/FDA-2021-S-0023-0053_attachment_1.pdf
[14] https://appropriations.house.gov/events/hearings/agriculture-hearing-fda-commissioner-robert-m-califf-md
[15] https://www.fda.gov/advisory-committees/committees-and-meeting-materials/2022-meeting-announcement-science-board-fda-06142022

needs to answer in order to establish a regulatory framework, and on what timelines does the agency expect to receive study results?

3. Please provide any analysis conducted by the agency comparing the risks of a regulated CBD marketplace with the risks of a growing unregulated CBD marketplace.

4. Please provide documents related to the withdrawal of the "Cannabidiol Enforcement Policy" document which completed OMB review in July 2020[16] but was never released by this Administration. Who was ultimately responsible for that decision?

5. We understand that the FDA has issued warning letters but what other enforcement or oversight has the FDA taken against CBD product manufacturers?

    a. Why has there been a low level of enforcement over the vast CBD products that are on the market today?

6. In July 2021, the FDA sent rejection letters to CBD companies objecting to their New Dietary Ingredient applications.[17] [18] One of the concerns the FDA cited in their letters was due to insufficient data on safety and efficacy surrounding CBD in a dietary supplement.[19]

    a. Please explain the rationale behind the lack of data when denying companies from attempting to safely come to market.
    b. What can be done to increase the amount of data available for future decisions?
    c. How many denials has the FDA issued for CBD products by companies that have attempted to submit a premarket "new dietary ingredient" notification?

Center for Tobacco Products (CTP)

Additionally, CTP has deviated from its original mission in the regulation of tobacco products. When Congress passed the 2009 Tobacco Control Act, the intent was for FDA's CTP to focus on setting product standards, reviewing applications in a timely and fair fashion, and regulating tobacco products through the lens of a tobacco harm reduction framework.

The market has changed significantly since 2009, made possible by the development of smoke-free nicotine products, including Electronic Nicotine Delivery Systems (ENDS). In fact, the agency's own website notes that these products play a role in harm reduction and cessation.[20]

The Agency has not met the challenge of making harm reduction in tobacco regulation a reality. For instance, the 2009 law carries requirements for CTP to review and issue decisions on

[16] https://www.reginfo.gov/public/do/eoDetails?rrid=130911
[17] https://www.regulations.gov/document/FDA-2021-S-0023-0053
[18] https://www.regulations.gov/document/FDA-2021-S-0023-0050
[19] *Id.*
[20] https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive#5

premarket tobacco product applications (PMTAs) within 180 days, but these applications have taken years to be reviewed. Just recently, certain PMTAs submitted in October 2019 and March 2020 did not receive marketing orders until October 2021 and June 2022, respectively.[21] These are not exceptions, but rather the clear trend across the applications reviewed and granted marketing orders[22], despite the agency receiving $712 million in industry user fees, and over $5.3 billion since 2015.[23]

In the midst of the struggles to handle the basic operational tenets of the Tobacco Control Act and apply them to 'deemed' tobacco products like ENDS, CTP now seems to focus more on massive additional undertakings like proposing a national ban on menthol cigarettes[24], a separate ban on flavored cigars[25], and, most recently, signaling that it would be moving forward with a nicotine cap on cigarettes[26] that would serve as a de facto ban.

Our frustration is compounded by the fact that Congress passed legislation providing FDA's CTP with clear authority to regulate synthetic nicotine vapor products that have become increasingly popular with kids.[27] Manufacturers of such products were required to submit applications in May 2022.[28] By July 13, 2022, products that did not receive marketing authorizations from CTP could not be manufactured, distributed, or sold without violating the law.[29] These compliance dates have come and gone and millions of synthetic nicotine products packing FDA marketing authorization still remain on the market and accessible to the public.

We encourage you to examine the planning and execution of CTP's ineffective approach in communicating to distributors and retailers which products are no longer able to be lawfully sold.

With these concerns in mind, we request responses to the following inquiries:

1. Please provide a detailed breakdown of how the user fees are being spent across all statutorily permitted activities.
    a. What percentage of fees are being directed to PMTA, substantial equivalence (SE), and modified risk tobacco product (MRTP) reviews, respectively?
    b. What percentage of fees are being used to develop regulations and policies?

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[21] https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency, https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-daily-e-cigarette-products

[22] https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders

[23] https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fee-assessment-formulation-product-class

[24] https://www.fda.gov/news-events/press-announcements/fda-proposes-rules-prohibiting-menthol-cigarettes-and-flavored-cigars-prevent-youth-initiation

[25] *Id.*

[26] https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco

[27] https://content.govdelivery.com/accounts/USFDA/bulletins/30f82ff

[28] https://www.fda.gov/tobacco-products/ctp-newsroom/reminder-electronic-submission-premarket-applications-non-tobacco-nicotine-products-due-may-14

[29] *Id.*

c. What percentage of user fees are deployed as grants to non-profit academic medical centers, research institutions, or non-profit foundations?
d. What percentage of fees are being used for public education campaigns?
e. What percentage of user fees are being directed to hiring staff at CTP?
    i. What percentage of these staff are working directly on review activities?

2. Please provide the following related to timeliness of processing applications:
    a. For PMTA authorizations the FDA has issued, what is the shortest timeframe in which a PMTA application has been authorized? What was the product category?
    b. For PMTA authorizations that the FDA has issued, what is the longest timeframe in which a PMTA application has been authorized? What was the product category?
    c. Based on past authorizations, what is the average time frame from submission for the FDA to authorization of a PMTA application?
    d. Based on past denials, what is the average time frame from submission for the FDA to deny a PMTA application?

3. Please review how CTP's ability to review product applications would be impacted if the menthol and nicotine caps regulations are finalized.
    a. What is the expected average review time for a PMTA with or without the new regulations?

4. How can the agency develop a more effective plan to remove unapproved synthetic products from shelves?
    a. Please provide a snapshot of the agency's enforcement resources, including field and enforcement staff.

5. How has the agency prioritized its enforcement resources to date in regard to this new statutory authority to regulate synthetic nicotine products?

6. How has the agency communicated with retailers, retail trade groups, and other organizations about the new law and the standards?
    a. Please provide copies of these communication documents and any materials given to these groups to share with their membership.

7. While one has not been communicated, does the agency currently have an enforcement discretion policy in place for synthetic nicotine products that do not have the requisite marketing authorizations but were accepted for review by July 14?

8. Please describe planned activities regarding communications, enumerating specific strategic aims, funding allocations, and staff FTE directed towards the following aims:
    a. What is the agency's plan to communicate to and educate the American people about the continuum of risk for tobacco products?

b. How will FDA educate Americans about the distinction between tobacco addiction and a nicotine addiction?

9. The FDA states that even though nicotine is addictive,[30] they also state "This toxic mix of chemicals—not nicotine—cause the serious health effects among those who use tobacco products, including fatal lung diseases, like chronic obstructive pulmonary disease (COPD) and cancer. Tobacco products containing nicotine pose different levels of health risk to adult users. Combustible products, or products that burn tobacco, are the most harmful." [31]
    a. What actions has the CTP undertaken to correct nicotine misperceptions among the general public, smokers, and the medical community?

We request responses to these inquiries by October 17, 2022. Thank you for your attention to this matter. We look forward to your response to the specified timeline above.

Sincerely,

H. Morgan Griffith
Member of Congress

Brett Guthrie
Member of Congress

[30] https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive
[31] *Id.*