ROGER WILLIAMS, TEXAS
CHAIRMAN

NYDIA M. VELAZQUEZ, NEW YORK
RANKING MEMBER

Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515–0315

November 20, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Califf:

The House Committee on Small Business (the Committee) writes regarding the Food and Drug Administration's (FDA) policy to not discuss its proposed rules with Congress. As part of the Committee's investigation into how agencies comply with the Regulatory Flexibility Act (RFA), the Committee sent the FDA a letter seeking a deeper explanation of a recently proposed rules' impact on small businesses.[1] In response, the FDA indicated it would not discuss proposed rules with Congress.[2] The Committee vehemently disagrees with the FDA's position and seeks a deeper explanation of how the FDA complies with Congressional requests for information.

Pursuant to House Rule X, this Committee has a duty to the House of Representatives and the American people to legislate and conduct oversight on "the problems of all small business."[3] The Committee cannot conduct oversight if the FDA continues to withhold requested information. Similarly, the Committee cannot draft adequately informed legislation without the FDA's input on substantive questions. As a general rule, *ex parte* communications between federal agencies and Congress are encouraged for Notice-and-Comment rulemakings such this.[4] Courts have found that better legislation and rules are created when agencies and Congress work together to create rules which implement legislation correctly.[5] This is valuable since agencies are tasked with implementing laws and have subject matter expertise in the relevant field, while Congress is responsible for passing the laws, thus having a better understanding of its intent and purpose.

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[1] Letter from Roger Williams, *et al.*, Chairman, H. Comm. on Small Bus., to Robert M. Califf, M.D., Commissioner, U.S. Food and Drug Admin. (Jun. 28, 2023).
[2] Letter from Erin O'Quinn, Acting Associate Commissioner for Legislative Affairs, U.S. Food and Drug Admin., to Roger Williams, *et al.*, Chairman, H. Comm. on Small Bus. (Oct. 18, 2023).
[3] Rules of the House of Representatives, Rule X(1), 118th Cong. (2022).
[4] MAEVE P. CAREY, *ET AL.*, CONG. RESEARCH SERV., IF12368, COMMUNICATIONS BETWEEN CONGRESS AND FEDERAL AGENCIES DURING THE RULEMAKING PROCESS (Mar. 30, 2023).
[5] *Sierra Club v. Costle*, 657 F.2d 298, 409 (D.C. Cir. 1981).

In your responses to the Committee, you indicated that small businesses and their comments were being heard in this rulemaking process.[6] While it is reassuring the FDA claims to have considered these interests, the purpose of our letter was to ensure that the FDA was, indeed, complying with their obligations to small businesses. Congress' authority to conduct oversight is inherent in Article I, sec. 1 which states: "All legislative powers herein granted shall be vested in a Congress of the United States." The United States Supreme Court has consistently affirmed Congress's authority to conduct oversight and investigations, holding that "the power of inquiry—with process to enforce it—is an essential and appropriate auxiliary to the legislative function."[7] Rule X of the Rules of the United States House of Representatives delegates this responsibility to standing committees.[8]

Denying the Committee the requested information prevents it from upholding and acting in furtherance of its legislative function, namely reviewing regulatory burdens imposed on small businesses by federal agencies and determining how they may be alleviated.[9] This includes the ability of this body to initiate investigations to inform itself about how existing laws function, whether new laws are necessary and if old laws should be repealed or altered. Responding substantively to the Committee's letter using information available in the docket, or information FDA makes available prior to the final rule, would in no way undermine the completeness of the docket or effectiveness of this rulemaking.[10]

It is important for agencies to examine small businesses interests—which make up 99.9 percent of all businesses in the United States—when passing any new rule. America's small businesses deserve to have their voices heard and considered. Seeing no valid reason for the FDA to withhold information on this rule, we reiterate our requests from our June 28, 2023 letter as well as request the following additional information as soon as possible but no later than December 4, 2023:

1. A copy of FDA's policy with regard to sharing information with Congress generally.

    a. An explanation of when this policy was implemented, and any policy which may have predated FDA's current policy regarding sharing information with Congress.

2. A copy of FDA's policy with regard to responding to Congressional oversight requests related to a proposed rule.

    a. An explanation of when this policy was implemented, and any policy which may have predated FDA's current policy regarding sharing information with Congress.

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[6] Letter from Erin O'Quinn, Acting Associate Commissioner for Legislative Affairs, U.S. Food and Drug Admin., to Roger Williams, *et al*., Chairman, H. Comm. on Small Bus. (Oct. 18, 2023).
[7] *McGrain v. Daugherty*, 273 U.S. 135, 174 (1927).
[8] *Trump v. Mazars USA, LLP*, 140 S. Ct. 2019 (2020); *McGrain v. Daugherty*, 273 U.S. 135 (1927).
[9] Rules of the House of Representatives, Rule X(1)(q)(1), 118th Cong. (2022).
[10] Administrative Procedure Act (APA), 5 U.S.C. § 553; *See also* JONATHAN GAFFNEY, CONG. RESEARCH SERV., LSB10558, JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT (APA) (Dec. 8, 2020).

3. An explanation of the legal reason the FDA believes sharing information with Congress regarding proposed rules is improper.

4. An explanation for FDA's rationale for not engaging in *ex parte* communications with Congress about proposed rules.

5. All training and supplemental support materials provided by the FDA to its employees regarding the Regulatory Flexibility Act.

6. An explanation for how the FDA accounts for the disparate costs incurred by small businesses compared to larger businesses, when conducting rulemaking.

For your convenience, the requests from the June 28, 2023 letter are copied below:

1. The analysis indicates that more than 115,000 small business retailers of flavored tobacco products will be impacted by the proposed rule.[11] Please quantify the revenue loss that banning the products under the proposed rule would have on average small business retailers by category (such as convenience stores, grocery stores, pharmacies, tobacconists, etc.).

2. Given the revenue loss referenced in question 1, how many small businesses do you estimate will be forced to close because of the proposed rule?
    a. What is your estimate on reduced employment figures associated with these small business closures?
    b. What is your estimate on reduced employment figures for businesses that remain open but with reduced revenues?

3. Given that many of the small businesses projected to be impacted by the rule are sources of food and pharmaceuticals in local communities, what data can the FDA share about the effect that the proposed rule will have on "food deserts" and "pharmacy deserts"?

4. The preliminary analysis only details one alternative — a delayed effective date — to minimize the proposed rule's burden on small businesses.[12] What other alternatives has the FDA considered or analyzed?

5. Given the FDA's expressed interest in the proposed rule's impact on minority communities, what data can the FDA share regarding the effect on minority-owned small businesses? Please include data related to the impact on revenue, employment, and viability for these businesses.

To schedule the delivery of your response or ask any related follow-up questions, please contact Committee on Small Business Majority Staff at (202) 225-5821. The Committee on

[11] DEP'T OF HEALTH & HUMAN SERV., FOOD & DRUG ADMIN., FDA-2021-N-1309, TOBACCO PRODUCT STANDARD FOR CHARACTERIZING FLAVORS IN CIGARS, 109 (May 2022).
[12] *Id*. at 112.

Small Business has broad authority to investigate "problems of all types of small business" under House Rule X. Thank you in advance for your cooperation with this inquiry.

In God We Trust,

Roger Williams
Chairman
Committee on Small Business

cc: The Honorable Nydia M. Velasquez, Ranking Member
Committee on Small Business