United States Senate
WASHINGTON, DC 20510

January 11, 2019

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

We are writing to request information regarding the effect of the partial federal government shutdown on the operations of the Food and Drug Administration (FDA). This shutdown will be, as of midnight, the longest in U.S. history and is hampering your agency's critical role in protecting the public health. The shutdown has severely limited federal oversight of the nation's food supply and medical products and may result in slower approvals for drugs and devices. While we appreciate the efforts of the agency and the tireless work of your staff to help mitigate the impact of the shutdown on the public health, we remain deeply concerned about the halt of vital regulatory and compliance activities at FDA. FDA plays a crucial role in ensuring the health and safety of families across the country, and it's important we fully understand how the ongoing shutdown has impacted its ability to fulfill that role.

While FDA has helped ensure that our nation has one of the safest food supplies in the world, foodborne disease results in 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths the United States each year.[1] The FDA Food Safety Modernization Act (FSMA), enacted in January 2011, provided FDA with new enforcement authorities to work towards reducing those numbers and preventing future food safety problems.[2] In 2018 alone, there were two major, multistate outbreaks of *E. coli* O157:H7; the first resulted in 210 illnesses, 96 hospitalizations, and five deaths across 36 states, and the second resulted in 62 illnesses and 25 hospitalizations across 16 states and the District of Columbia.[3]

However, during the shutdown, FDA's inspectorate is unable to conduct any activities deemed non-critical, resulting in diminished oversight of many foreign and domestic food facilities. As the shutdown enters its fourth week, we are concerned that the agency will soon be unable to determine which food facilities pose an "imminent threat to health and life."[4] Though FDA is able to use appropriated funds to support high-risk food recalls when products endanger consumers and patients, and respond to any outbreaks related to foodborne illness during the shutdown, we are concerned about the agency's ability to detect and address otherwise preventable food safety issues before they occur. FDA field staff have voiced fears about immediate threats to health and safety as a result of the shutdown, including a consumer safety officer in FDA's Stoneham, Massachusetts, office: "When you go out to a restaurant or a

[1] https://www.cdc.gov/foodborneburden/estimates-overview.html
[2] https://www.fda.gov/newsevents/publichealthfocus/ucm239907.htm
[3] https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html; https://www.cdc.gov/ecoli/2018/o157h7-11-18/index.html
[4] https://twitter.com/SGottliebFDA/status/1076329985143640064

grocery store, the American public trusts it. There is a higher risk of injury or death in a potentially very, very serious way."[5]

We are also concerned about the effects of the shutdown on the agency's medical product review process. During the shutdown, FDA is legally prohibited from accepting new submissions that require industry user fee payments,[6] which support the review and approval of applications for innovative new prescription drugs, generic drugs, and medical devices.[7] As a result, the agency will likely receive a large influx of applications from drug and device makers following the conclusion of the shutdown, requiring the agency to triage review activities and probably causing a backlog in the approval process.

Although FDA is currently able to support ongoing medical product review processes with carryover user fee funding from Fiscal Year (FY) 2018,[8] the agency estimates the FY 2018 balances for these programs will run out if the shutdown continues. The first user fee program anticipated to burn through carryover funding is the Prescription Drug User Fee Act (PDUFA) program, which funds the review of new drugs. As of January 7, PDUFA has about one month of funding remaining in the FY 2018 balance, while the remaining user fee programs were estimated to have between one and two months of funding left.[9] Should the remaining FY 2018 balance for these programs expire, the vast majority of FDA's ongoing product review functions will cease to continue, and user fee-funded employees (just under half of the agency) would no longer be paid.

Given that, due to the shutdown, FDA is currently unable to perform essential regulatory and compliance activities, we want to ensure the agency is doing everything it can to fulfill its critical public health mission at this time. In order to better understand the impact of the shutdown on public health and FDA staff, and in light of the fact that President Trump has indicated he is willing to continue the government shutdown for months or years, we request answers to the following questions by January 18th:

1. How has the agency scaled back food and medical product lab analysis, surveillance, and inspection activities during the shutdown?
2. Which inspections of domestic food facilities does the agency plan to reinstate in the coming days, and what percentage of the currently ceased inspectional activities will be reinstated prior to the end of the shutdown?
3. Please provide a detailed overview of the increase in anticipated backlog of applications for new medical products at this time, and for each additional week of the shutdown, including, to the agency's best estimates, when normal functionality can be expected to resume.
4. Please provide an update on remaining FY 2018 carryover funds, and their anticipated burn rate, for user-fee funded programs, including prescription drug, generic drug, tobacco product, animal drug, biosimilar, and medical device review activities.

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[5] https://www.cnn.com/2019/01/08/health/fda-employee-concerns-shutdown/index.html
[6] https://www.fda.gov/AboutFDA/WorkingatFDA/ucm629100.htm
[7] https://crsreports.congress.gov/product/pdf/R/R44576
[8] https://twitter.com/SGottliebFDA/status/1080632053220233216
[9] https://twitter.com/SGottliebFDA/status/1082441112005066755

5. Please provide an update on the status of the guidance you released to FDA's field force investigators and any additional steps FDA plans to take to mitigate financial burdens incurred by the inspectorate as a result of the shutdown.
6. What are FDA's plans to address financial hardship sustained by excepted and furloughed employees as a result of the shutdown? Is FDA aware of any employees that have left the agency as a result of the shutdown?
7. How will the freeze on unfunded employee recruitment activities and new employee onboarding affect your strategic hiring plan for the agency?
8. Please detail any delays in normal operations that you anticipate to occur once the shutdown is over. Will FDA be able to immediately resume all suspended activities upon receiving full funding for FY 2019?

We recognize FDA's efforts to mitigate the impact of this government shutdown on the public health and its employees. However, we remain alarmed that the continued shutdown will result in increasingly harmful effects on the agency's employees and the safety and security of the nation's food and medical products.

Thank you for your immediate attention to this important issue. If you have any questions, please contact Katlin McKelvie Backfield of the United States Senate Committee on Health, Education, Labor, and Pensions at (202) 224-7675.

Sincerely,

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United States Senator

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