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May 13, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

We write to express concern over the lack of transparency related to the budget for food programs at the Food and Drug Administration (FDA). As you know, the Office of Regulatory Affairs (ORA) receives approximately 70 percent of the funds Congress appropriates for the food program. We are concerned that ORA's substantial overhead and lack of transparency and accountability in resource management present obstacles to the efficient and effective use of ORA's appropriated resources and fulfillment of the prevention mandate of FDA's food program.

From FY2018 to FY2019, ORA's food funding was essentially flat at \$732 million. However, key indicators of performance declined significantly. For instance: domestic inspections decreased 18 percent, resulting in over 1,500 fewer inspections; visual exams of imported food products declined 25 percent, resulting in 29,000 fewer exams; and sampling of imported products decreased 21 percent, resulting in 3,500 fewer samples being taken for testing.

During FY2019, Congress funded 2,179 food full-time equivalent (FTE) positions for ORA, but ORA allocated only 785 positions for food safety compliance and inspection staff. At the end of the 2019 calendar year, over 100 – over 13 percent -- of these positions were vacant.

We have been advised that the method ORA uses to calculate operational tasks such as inspections and enforcement assumes that each inspection and compliance staff member spends 950 hours per year (out of a potential work year of 2080 hours) on these operational tasks, meaning it takes over two field staff to perform the duties of one FTE. Also, a significant percentage of ORA human food functions performed in both field offices and FDA headquarters

are deemed non-operational and, unlike operational FTEs, there is no timekeeping to document how ORA's non-operational food resources are spent.

The FDA's Center for Food Safety and Nutrition (CFSAN) is ultimately responsible for safeguarding the food supply, especially as it relates to the implementation of the Food Safety Modernization Act (FSMA). However, CFSAN has no role in planning the use of ORA's non-operational resources, which results in a lack of transparency even within FDA on how ORA uses its resources allocated for the food program.

As part of our process of developing the FDA budget for FY 2022, please respond to the following questions in a timely manner.

- 1) What accounts for the significant declines from FY 2018 to FY 2019 in the number of domestic inspections, import exams and import analyses performed by ORA?
- 2) What accounts for the vacancies in ORA food inspection and compliance positions?
- 3) What are the staffing levels and vacancy rates in all other ORA positions that play roles related to food?
- 4) To the extent ORA was not able to staff its food positions at the FTE level for which dollars were appropriated in FY 2019 and FY 2020, please provide details on how ORA allocated these funds.
- 5) Why are ORA inspection and compliance staff assumed to devote only 950 hours per year to operational work? How is the remainder of the time allocated?
- 6) For FY 2019 and FY 2020, please provide detailed, quantitative information on the ORA organizational units and functions, staff positions, and FTEs engaged in operational and non-operational work related to the food program.
- 7) What is the decision-making process within the FDA for how food resources are allocated between operational and non-operational functions? Also, what is the decision-making process for how food resources are allocated among program areas, such as domestic and foreign inspections, import oversight, and laboratory analysis?
- 8) How does ORA evaluate and report the extent to which it completes the tasks in the annual work plan? Please provide any such reports for FY 2015 – FY 2020.
- 9) Please provide estimates of the average cost of ORA's domestic and foreign inspections, the methodology for developing these estimates, and a comparison of ORA's average inspection costs with the costs of state inspections.

Acting Commissioner Janet Woodcock, M.D.
May 13, 2021
Page 3

Thank you for your attention to this issue. Please provide responses to these questions as soon as possible.

Sincerely,

A handwritten signature in black ink that reads "Rosa L. DeLauro". The signature is written in a cursive style with a large, stylized "R" and "D".

Rosa L. DeLauro
Chair
House Appropriations Committee

A handwritten signature in black ink that reads "Sanford D. Bishop, Jr.". The signature is written in a cursive style with a large, stylized "S" and "B".

Sanford D. Bishop, Jr.
Chairman
House Appropriations Subcommittee on
Agriculture, Rural Development, Food and
Drug Administration, and Related Agencies