

October 6, 2022

Dr. Jane Henney  
Chair, Independent Expert Panel - FDA Human Foods Program  
The Reagan-Udall Foundation  
1333 New Hampshire Ave., NW - Suite 420  
Washington, DC 20036

Dear Dr. Henney:

The undersigned coalition appreciates the opportunity to submit comments to the Reagan-Udall Foundation as part of its review of the foods program at the Food and Drug Administration (FDA). It has become evident in recent years that the foods program is in need of a significant culture change that would allow for a focus on illness prevention with improved governance, accountability, and transparency.

The review panel is likely aware of the April 25 letter signed by many of the groups represented in these comments that highlighted the structural, governance, and performance problems in the FDA foods program and its effect on the ongoing implementation of the Food Safety Modernization Act (FSMA) and the execution of the New Era of Smarter Food Safety blueprint.

The success of these, and all, initiatives depend on all major foods program units – the Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) – working together seamless with their state partners and with a common strategic direction, clear priorities, sound resource management, and internal accountability. Success also requires transparency and robust engagement with industry, consumer groups, state associations, and other stakeholders.

As part of our letter, we urged FDA Commissioner Robert Califf to create an empowered deputy commissioner for food position that would lead a unified foods program. This position would have direct line authority over all major program components, including CFSAN, CVM, and the relevant components of ORA.

The need for reforms within the FDA foods program is extensive and will not be solved by the appointment of an empowered deputy commissioner position alone. However, it would bring focused leadership and accountability, and a unified structure that clearly establishes internal roles and responsibilities and strengthens the program's ability to dialogue effectively with its many internal and external stakeholders. The empowered deputy commissioner and unified structure would also allow for streamlined decision-making and swift responses that would benefit all stakeholders, both in urgent matters and for daily operations.

Finally, this structural reform would enable enhanced transparency across the program, including: clearly documenting where resources are invested within the foods program through a transparent and consistent methodology; engaging in the open sharing of non-proprietary information, both internally and with external stakeholders; and publishing the analyses that form the basis of regulatory decisions.

While we recognize that CVM is excluded from your review, we are concerned that this exclusion demonstrates FDA’s unwillingness to address difficult internal issues involving structure and accountability, and could be an attempt to influence this panel’s recommendations. It also demonstrates a lack of understanding of how the food system works. Virtually every element of CVM’s program relates in some way to the food system, including the animal drug approval program, which mainly applies to human food animals, and the regulation of animal feed, which affects both human and animal health. Excluding CVM from this review increases the potential that this panel’s final report and recommendations will be incomplete.

We appreciate your consideration of these comments and the panel’s overall work on this critical review of the FDA foods program.

Sincerely,

<b><u>Consumer/Public Health Groups</u></b>	<b><u>Industry Groups</u></b>
Antibiotic Resistance Action Center (GWU)	American Bakers Association
Center for Biological Diversity	American Frozen Food Institute
Center for Food Safety	Consumer Brands Association
Consumer Federation of America	Corn Refiners Association
Consumer Reports	FMI – The Food Industry Association
Environmental Defense Fund	Global Cold Chain Alliance
Environmental Working Group	International Fresh Produce Association
Friends of the Earth	National Confectioners Association
Healthy Babies Bright Futures	National Fisheries Institute
Johns Hopkins Center for a Livable Future	National Grocers Association
National Consumers League	National Pasta Association
Natural Resources Defense Council	National Restaurant Association
STOP Foodborne Illness	National Seasoning Manufacturers Assoc.
	North American Millers’ Association
<b><u>State and Local Government</u></b>	Peanut and Tree Nut Processors Association
Association of Food and Drug Officials	Refrigerated Foods Association
	SNAC International
	Western Growers