From: Principal Deputy Commissioner
To: FDA-Wide
Subject: Work continues on the Human Foods Program proposal
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Janet Woodcock

A Message from the Principal Deputy Commissioner

Dear Colleagues,

Earlier this year, the Commissioner announced a proposal for a unified Human Foods Program (HFP) and new model for the Office of Regulatory Affairs (ORA). This announcement has generated a considerable amount of interest both internally and externally. I recognize that many employees have questions and concerns about the future changes and have offered ideas for improving the way we work. I am grateful to all those who have participated in the town hall meetings, attended a listening session, asked a question or shared their comments on the proposal.

As Chair of the Implementation and Change Management Group (ICMG), I am committed to providing you with regular updates to directly address the questions and concerns we've been hearing the most. Here is more on what we've been working on, and what you can expect in the next couple of months.

The ICMG is primarily made up of core members from the Office of the Commissioner, Center for Food Safety and Applied Nutrition, Office of Food Policy and Response, ORA, and Center for Veterinary Medicine. There are several workstreams with representation from impacted centers and ORA. The ICMG also includes staff from my office and a representative from the Center for Drug Evaluation and Research to provide a bridge to adjacent medical products work. Liaisons from offices like the Office of Chief Counsel, Office of External Affairs, Office of Operations, and Office of Policy, Legislation, and International Affairs also participate to share their perspectives on the change process.

When we began meeting last December, the ICMG kicked off by talking about the strengths and challenges of the current program. The conclusions were unanimous: our dedicated staff and unmatched expertise are our greatest assets. Food in our country is safe to eat because the FDA's HFP is committed to accomplishing the mission despite the challenges we face.

There was a good deal of agreement on the challenges, too. First and foremost, insufficient personnel, financial, and information technology resources, and a constantly growing workload are driving the need for the future HFP to better prioritize activities through a transparent, centralized process. The future HFP should perform analysis of various risks to public health (e.g., microbial, chemical, nutritional) across the portfolio, prioritize activities based on the severity of those risks and the tools available to manage them, and allocate resources according to the most effective risk management.

Given that the needs are continuously evolving and outpace available resources, including funding, the program should be clear about what can and cannot be accomplished. Further, we need to reframe how we connect the HFP's budget to specific activities to be clearer about how we are using our existing resources and the resources we believe are needed to support the program's work.

How we advance nutrition, conduct inspections and compliance activities, facilitate training, and utilize our laboratories could all use some fine tuning. And we need to fully realize the vision of an Integrated Food Safety System. Our ability to make the necessary changes will directly impact how the agency regulates various commodities going forward. In order to tackle these unique challenges, we have several workstreams, which you can learn more about on the ICMG site on insideFDA.

The HFP and ORA are faced with the challenge of having more work to do than people to do the work, and through this process,

the ICMG's goals are to make sure that the proposed program operates with clear priorities, is managed by leaders with clear decision-making responsibilities, and provides our dedicated staff with the training and resources they need to do their jobs effectively and efficiently.

The ICMG recognizes the incredible talent and dedication of all our colleagues in the HFP and ORA. The work of the ICMG, as well as your input, will help to inform the design of the new HFP and ORA model. In the next couple of months, the agency plans to announce the proposed organizational structures for the new HFP, as well as a new model for ORA. As the ICMG continues its work, we will be reaching out to additional subject matter experts across the agency for their perspectives and counsel. There will also continue to be opportunities to provide input on the details of how the program will operate, and of course, many chances to have your questions answered along the way.

Please continue to send your questions and feedback to fda-comments@fda.hhs.gov. This information is shared with me and the rest of the ICMG to inform our work and is greatly valued and will be considered.

Sincerely,
Janet

Janet Woodcock, M.D.
Principal Deputy Commissioner