Council for Responsible Nutrition
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August 25, 2026

Donald A. Prater, D.V.M.
Acting Deputy Commissioner for Food
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Request for clarification regarding FDA's "Simple Reform" and the inspectional workforce

Dear Dr. Prater:

The Council for Responsible Nutrition (CRN)[1] respectfully requests clarification regarding the Food and Drug Administration (FDA)'s planned "Simple Reform" reorganization and its implications for the inspectional workforce, particularly for inspections conducted under the Human Foods Program.

On July 29, 2026, FDA published a Federal Register notice revising its Statement of Organization, Functions, and Delegations of Authority to reflect plans to "centralize and enhance key functions across the agency" to reduce duplication, improve efficiency, and promote alignment.[2] The notice also lists the Office of Inspections and Investigations with its distinct product- and program-focused inspectorates. These include separate inspectorates for animal food, human and animal drugs, and human food, with the Office of Human Food Inspectorate further organized into Central, East, and West offices and a Global and Specialty Human Food Inspectorate.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing the dietary supplement and functional food industry. Bringing together manufacturers, ingredient suppliers, and service providers, CRN unites its member companies around a shared commitment to science, transparency, and responsible business practices—advancing a strong, credible marketplace that supports consumer health and industry growth. Through strategic advocacy, self-regulatory leadership, voluntary guidelines, and evidence-based communications, CRN ensures that responsible companies are recognized, protected, and positioned to innovate and compete. Learn more at crnusa.org.

[2] Department of Health and Human Services. Food and Drug Administration. Statement of Organization, Functions, and Delegations of Authority. 91 FR 47835 (July 29, 2026). https://www.federalregister.gov/documents/2026/07/29/2026-15297/statement-of-organization-functions-and-delegations-of-authority#dates

However, recent reporting appears inconsistent with FDA's public description of its inspections workforce model. A July 28 NOTUS article reported that, beginning October 1, FDA would stop assigning specialized field inspectors to specific subject areas and instead have them operate as generalists across multiple FDA-regulated products.[3] A July 31 Food Safety Tech article similarly reported a shift from specialized product roles to generalist investigators.[4] However, the Pink Sheet quotes an FDA source that the generalist portion of the plan was not implemented as part of the reorganization,[5] and FDA's August 3 FDA Voices post, "Investing in FDA's Inspectional Enterprise," expressly states that the next-generation Office of Inspections and Investigations workforce model, "is not a move to generalists" and is designed to strengthen specialized expertise.[6] But the post also describes cross-functional development intended to enable investigators to work across different product areas when needed, which would suggest a return to a generalist multi-category inspectorate.

CRN believes FDA's 2017 implementation of Program Alignment was moving the agency in the right direction. Program Alignment shifted FDA's field operations from a geographic management model to a program-based model and placed investigations and compliance functions into product-focused programs, including human food. The initiative recognized that FDA-regulated product categories involve distinct statutory and regulatory frameworks, manufacturing processes, current good manufacturing practice requirements, technologies, and compliance risks. For instance, the competencies required for compliance with—and conducting inspections is pursuance of—21 CFR Part 111 (dietary supplements) and 21 CFR Part 211 (drugs) are vastly different, and conformance to Part 111 is different that 21 CFR Part 117 (food). Developing investigators with product-category expertise therefore promotes more technically informed inspections, greater consistency, and more effective oversight. A return to a generalist model for the inspectorate could undo the substantial effort and institutional knowledge developed through Program Alignment and disserve both the industries FDA regulates and the consumers the agency protects.

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[3] NOTUS, "The FDA Is Officially Codifying DOGE-Era Changes" (July 28, 2026). Available at: https://www.notus.org/agencies/fda-officially-codifying-doge-era-reorgnization-inspectors

[4] Food Safety Tech, "The FDA is implementing a major reorganization plan called 'Simple Reform' on October 1, 2026" (July 31, 2026; updated Aug. 10, 2026). Available at: https://foodsafetytech.com/news_article/the-fda-is-implementing-a-major-reorganization-plan-called-simple-reform-on-october-1-2026/

[5] Pink Sheet, “US FDA ‘Simple Reform’ Reorg Approved; Inspection ‘Generalist’ Changes Coming Later” (July 31, 2026). Available at: https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/us-fda-simple-reform-reorg-approved-inspection-generalist-changes-coming-later-XZJ2GFQHYJCMBGU3W57X55EGIA/

[6] FDA Voices, "Investing in FDA's Inspectional Enterprise" (Aug. 3, 2026). Available at: https://www.fda.gov/news-events/fda-voices/investing-fdas-inspectional-enterprise

We recognize that the Food Safety Tech article was updated on August 10 to report that the Human Foods Program is not affected by Simple Reform. That update is helpful, but it also underscores the need for an authoritative FDA explanation of the scope and practical effects of the reorganization. Regulated companies depend on a technically capable and predictable inspectorate, and clarity regarding investigator qualifications and assignments is important for inspection readiness and confidence in consistent oversight.

Accordingly, CRN respectfully asks FDA to clarify:

1. Whether Simple Reform applies to investigators who conduct human food and dietary supplement inspections and, if not, which inspectorates or product areas are affected;
2. Whether investigators will continue to be assigned principally within product-specific or program-specific areas, or may routinely conduct inspections across different FDA-regulated product categories;
3. How FDA distinguishes the cross-functional capabilities described in the FDA Voices post from a generalist inspection model; and
4. What safeguards, training, certification, supervision, or subject-matter support FDA will use to preserve specialized expertise, including expertise in dietary supplement and food current good manufacturing practice requirements, when assigning and conducting inspections.

CRN would appreciate FDA's clarification of these issues and, if available, any organizational charts, implementation materials, or workforce policies that explain how Simple Reform will affect investigator assignments and technical specialization. A clear public explanation would help reconcile the differing accounts and provide regulated stakeholders with a more predictable understanding of FDA's inspectional approach.

Thank you for your consideration. We would welcome the opportunity to discuss these questions with you and appropriate representatives of the Human Foods Program and the Office of Inspections and Investigations.

Sincerely,

Steve Mister
President & CEO