

# Regulatory Rollback and Rebrand of FDA's Human Foods Program

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May 22, 2025

Over the past three months, the U.S. Food and Drug Administration (FDA) Human Foods Program (HFP) has begun efforts both to deregulate and to retool prior agency programs to fit the Make America Healthy Again (MAHA) agenda. Specifically, FDA leadership, Commissioner Dr. Martin Makary and Acting Deputy Commissioner for Human Foods, Kyle Diamantas, has announced a series of sweeping initiatives—ranging from potential deregulation to changes to the well-established “generally recognized as safe” (GRAS) pathway for food ingredients—with the net intent of advancing Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr.’s focus on food. Collectively, these MAHA proposals and initiatives have the potential to significantly change FDA’s regulation of food, food ingredients, dietary supplements, and infant formula into the future. Stakeholders would be well served in monitoring these developments and engaging, where appropriate, in the numerous opportunities for providing comments and feedback.

We summarize the key developments below.

## ***Deregulatory Calls to Action***

The HHS and FDA on May 13 [announced](#) the opening of a request for information (RFI) asking stakeholders to identify regulations or guidance that will be considered for potential elimination. The [stated goal](#) is to ensure that the “regulatory framework is clear, predictable, and allows providers to focus on preventing and treating chronic disease instead of clearing unnecessary regulatory hurdles,” with a commitment “to maintain and even strengthen the regulations that genuinely protect the public.” The RFI asks for suggestions across all product categories by July 14, 2025.

This announcement is consistent with the Trump administration’s earlier actions advancing its deregulatory intent, beginning with the January 24 [memorandum](#) placing a freeze on new or pending rules, the January 31 “10-for-1” [executive order](#) mandating that for every new rule or guidance, agencies target at least 10 others already existing for repeal, and the February 19 Department of Government Efficiency (DOGE) Deregulatory Initiative [executive order](#) calling for the rescission of existing regulations and the review of new regulations by DOGE and the Office of Information and Regulatory Affairs (OIRA).

## ***FDA Human Foods Program Initiatives***

- [GRAS Reform](#): In a series of comments, Secretary Kennedy has made clear that revamping the

GRAS pathway is a priority. On March 10, 2025, Secretary Kennedy directed FDA to explore rulemaking to eliminate the pathway for companies to self-affirm that food ingredients are GRAS; separately, Secretary Kennedy has mentioned the possibility of eliminating GRAS altogether.

GRAS is a statutory carveout from the premarket approval requirement (i.e., a food additive petition) for new food ingredients that was added to the Federal Food, Drug, and Cosmetic Act in 1958. Over the past 60+ years, FDA has changed its approach more than once for establishing whether an ingredient is GRAS. However, since 1997, FDA has relied on a voluntary notification process (finalized under a 2016 rule) wherein a company can share its information supporting GRAS status with the agency for review and [public posting](#), or alternatively may retain information supporting such status without sharing, colloquially known as “self-affirmation.” While there has been some mention of a fast-moving rulemaking to eliminate self-affirmation, to date there has been no actual proposal. Eliminating the self-affirmation pathway may require FDA to grapple with its longstanding position that notification is voluntary and will require the agency to consider how to address the large number of self-affirmed ingredients currently on the market. Eliminating GRAS entirely will require close coordination with Congress. Ultimately, changes to the GRAS pathway could have sweeping impacts, and it will be important for stakeholders to be attentive to proposals and opportunities for comment.

- **[Post-Market Food Chemical Review Program](#)**: On May 15, 2025, FDA announced plans to launch a systematic review process for food chemicals already on the market along with an evidence-based prioritization scheme for identifying chemicals for review. FDA stated that it also intends to update its list of chemicals already under review on the agency's [website](#). The details have yet to be announced. However, it is worth noting that, in many ways, the announcement incorporates much of (1) the agency's priority deliverables [announced](#) in December 2024 for food chemical safety and (2) FDA's August 2024 [proposed process](#) for conducting post-market assessments of chemicals in foods, including GRAS ingredients, food additives, color additives, food contact substances, and contaminants, which was already planned for the end of FY 2025. Notably, the announcement does not address FDA's already initiated review of environmental contaminants under the 2021 [Closer to Zero](#) initiative.
- **[Food Dyes](#)**: On May 9, 2025, FDA granted three new color additive petitions (CAPs) for food colors derived from natural sources: butterfly pea flower extract (blue), CAP submitted 2024; calcium phosphate (white), CAP submitted 2023; and galdieria extract (blue), CAP submitted 2021. These approvals are consistent with FDA's April 22, 2025 [announcement](#) on efforts to phase out petroleum-based synthetic dyes while providing industry with natural alternatives. Per this announcement, FDA is initiating the process to revoke authorization of two food dyes (Citrus Red No. 2 and Orange B) and working with industry to eliminate six other dyes (Green No. 3, Red No. 40, Yellow No. 5, Yellow No. 6, Blue No. 1, and Blue No. 2) by the end of 2026. FDA has also requested that food companies accelerate Red No. 3 removal from food and ingested drugs sooner than the 2027 and 2028 deadlines [announced](#) by FDA in January 2025.
- **[Infant Formula Nutrient Review](#)**: On May 14, 2025, FDA published an RFI to begin the nutrient review process for infant formulas. Specifically, FDA is asking whether there is a need to revise the existing nutrient requirements, taking into consideration any new scientific data or information related to infant formulas including international infant formula standards. The RFI is part of

Operation Stork Speed launched in March of this year, whereby FDA also intends to increase testing for heavy metals and other contaminants in infant formula and other foods children consume, extend the personal importation policy for infant formula, and encourage manufacturers to increase transparency and provide clearer labeling. The RFI and Operation Stork Speed build upon the agency's [prior efforts](#) to help increase market diversity and enhance the U.S. infant formula supply to mitigate future shortages as directed by Congress through the Food and Drug Omnibus Reform Act of 2022. Interested stakeholders have through September 11, 2025 to respond to the RFI.

- **[Front-of-Package Labeling](#)**: On May 9, 2025, FDA published a notice extending the comment period for FDA's Front-of-Package Nutrition Labeling [proposed rule](#). The proposal, issued January 16, 2025, would require nutrition information on the front-facing, principal display panel or bulk food labeling of most foods that already include Nutrition Facts labeling. The front-of-pack labeling, if finalized, would consist of a compact informational box containing certain standardized nutrient information (i.e., saturated fat, sodium, and added sugars) and interpretive language (low, high) on the principal display panel in a specified format. The proposed rule has potentially far-reaching implications for packaging. Stakeholders now have until July 15, 2025 to comment on topics, including the size, format, and substance of the proposed front-of-pack "Nutrition Info" box, the proposed exemption of dietary supplements, and the interpretive descriptions language.
- **["Healthy" Rule Webinar](#)**: On April 10, 2025, FDA held its long-awaited webinar on the December 2024 updated "Healthy" nutrient content claim [final rule](#). As FDA described in the webinar, and consistent with the previously finalized rulemaking, the updated claim framework relies on a food group-based approach, known as "food group equivalents," where products bearing the claim must contain a meaningful amount of at least one food group recommended by the [Dietary Guidelines for Americans](#) (vegetables, fruit, grains, dairy, or protein) and meet certain limits for added sugars, saturated fat, and sodium. Manufacturers have until February 25, 2028 to comply with the requirements, although those that would like to make the claim can already do so if they meet the updated criteria.

### ***Expanded Unannounced Foreign Inspections***

- As we [reported on earlier](#), on May 6, 2025, FDA [announced](#) its intention to expand the use of unannounced inspections at foreign manufacturing facilities for products under FDA authority, including foods and dietary supplements. FDA's announcement aligns with the Trump administration's efforts to increase oversight of foreign manufacturers with shorter, impromptu inspections while promoting domestic manufacturing. It is unclear whether FDA has the resources to implement this initiative. Companies with manufacturing facilities abroad should review internal procedures and initiate rigorous inspection readiness training as soon as possible, particularly for facilities that have not undergone an FDA inspection recently.

## **CONTACTS**

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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