The Trump Administration's First Unified Agenda for FDA Promises Major Changes for the GRAS Pathway, Food Ingredients, and Cosmetics

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The Make America Healthy Again (MAHA) program and implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) will keep the U.S. Food and Drug Administration (FDA) hopping for at least the next year, according to the recently-issued "Spring" Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Office of Information and Regulatory Affairs (OIRA), part of the Office of Management and Budget, publishes the Unified Agenda twice each year. It identifies the proposed and final rules that federal agencies expect to advance over the next twelve months. The Spring 2025 version, the first published under the Trump administration, provides an early indication of the Administration's regulatory and deregulatory priorities. FDA is charged with multiple MAHA- and MoCRA-driven initiatives that could have significant implications for the food, dietary supplement, and cosmetics industries.

What's New and Significant

The newly updated Unified Agenda highlights more than a dozen FDA and U.S. Department of Agriculture (USDA) rulemakings affecting human foods, dietary supplements, and cosmetics, several of which reflect changes from the Fall 2024 Unified Agenda. Key developments include:

- **GRAS Framework Overhaul.** A new proposed rule on substances "Generally Recognized as Safe" (GRAS) would require the mandatory filing of GRAS notices for human and animal food uses. If adopted, this approach would effectively eliminate the private GRAS self-affirmation pathway, marking a significant departure from longstanding practice and creating new hurdles for introducing novel food ingredients or continuing to use ingredients not previously disclosed to FDA. The proposed rule may also impact the existing notification program for food-contact substances such as those used in packaging or cookware. This proposal aligns with the MAHA Commission's broader strategy to phase out the GRAS self-affirmation process (see B&D alert here). The Unified Agenda's description does not clarify what the rule, once adopted, will mean for the many self-affirmations of GRAS status that have occurred without review by FDA, as allowed under current law. FDA projects the release of the proposal in October 2025.
- **Cultivated Meat Labeling.** USDA's proposed rule on labeling of meat and poultry products produced using animal cell culture technology has been moved to the agency's "long-term actions." The rule was previously scheduled for publication in December 2024, following USDA's 2021

advance notice of proposed rulemaking (see B&D alert here). The shift suggests that labeling requirements for cultivated meat are unlikely to advance within the next year.

- **Front-of-Package Nutrition Labeling.** As called for in the MAHA Commission Report, the Unified Agenda retained FDA's front-of-package nutrition labeling rulemaking, first proposed at the close of the Biden Administration. While the proposal is aligned with ongoing initiatives to increase transparency in food labeling, it remains unclear whether the current Administration will carry forward the existing scheme or revise it. FDA anticipates issuing the final rule in May 2026.
- **N-acetyl-L-cysteine (NAC) in Supplements.** The Unified Agenda maintains a proposed rule that would authorize the use of NAC as an ingredient in dietary supplements. FDA had previously taken the position that NAC was excluded from use in supplements due to its prior approval as a drug, a conclusion that prompted litigation and the issuance of an enforcement discretion policy. The proposal, originally scheduled for May 2025, is now targeted for January 2026.
- **Formaldehyde in Hair Smoothing Products.** The Unified Agenda includes a proposed rule that would prohibit or restrict the use of formaldehyde and formaldehyde-releasing chemicals as an ingredient in hair smoothing and straightening products. This action follows longstanding safety concerns and aligns with FDA's broader efforts under the MoCRA to address high-risk cosmetic ingredients. The proposal, originally scheduled for March 2025, is now targeted for December 2025.
- **Fragrance Allergen Disclosure.** FDA also plans to move forward with a proposed rule requiring the identification of specified fragrance allergens on cosmetic product labels. This initiative responds to MoCRA's mandate for greater transparency in fragrance ingredient disclosures and mirrors similar labeling requirements already in place in the European Union. FDA projects the release of the proposal in May 2026.
- **Good Manufacturing Practices (GMPs).** The Unified Agenda continues to list FDA's work on a proposed rule establishing good manufacturing practice standards for cosmetic product facilities. These standards, also mandated by MoCRA, are intended to ensure product safety and quality. However, FDA moved the GMP Rule from the standard Unified Agenda to the long-term actions list, which means that the Agency is unlikely to publish the NPRM in the next 12 months. MoCRA directed FDA to adopt proposed GMP regulations by December 29, 2024, and final good manufacturing practice regulations by December 29, 2025. This action could open FDA to a challenge for failure to meet its statutory deadlines.
- **Asbestos in Talc-Containing Products.** Finally, FDA retains a proposal to establish standardized testing methods for detecting asbestos in talc-containing cosmetic products. FDA published a proposed rule in December 2024. The Unified Agenda predicts the final rule's publication in March 2026. For more information, see B&D's news alert.

Implications for Stakeholders

- Ingredient suppliers, food additive manufacturers, and food processors will need to reassess how they bring new food ingredients to market under GRAS. If mandatory notification is adopted, traditional self-affirmation avenues may no longer be viable without FDA review.
- Labeling, marketing, and regulatory compliance will likely be subject to new levels of scrutiny. Firms must track deadlines, public comments, and possible new audit or reporting requirements.

- Cosmetics manufacturers and ingredient suppliers should prepare for stricter rules under MoCRA – especially for formaldehyde/formaldehyde releasers in hair products, talc impurities, and fragrance allergen disclosure. R&D and formulation strategies may need early adjustments.
- With federal rulemaking accelerating, state legislatures may also move quickly to impose ingredient bans, warning labels, or definition changes. Federal and state paths are likely to diverge in some respects.

What's Next

The Spring 2025 Unified Agenda highlights both immediate and longer-term regulatory shifts for FDA- and USDA-regulated industries. In the food and dietary supplement space, attention will center on FDA's forthcoming GRAS proposal, which could fundamentally reshape the pathway for introducing new ingredients by making FDA notification mandatory. Companies should also watch for continued movement on the front-of-package nutrition labeling rule, though the Administration's direction remains uncertain, and for deferred timelines on dietary supplement issues such as NAC. USDA's decision to move its cultivated meat labeling rule to long-term status suggests that formal requirements in this area are not imminent.

In the cosmetics arena, FDA's implementation of MoCRA will be a focal point, with anticipated actions on formaldehyde in hair products, asbestos in talc-containing cosmetics, and fragrance allergen disclosures. These rulemakings may bring significant changes for manufacturers and ingredient suppliers, even as questions remain about the Administration's priorities and timelines.

Companies involved in the manufacture, import, or use of food ingredients, dietary supplements, or cosmetics should assess how FDA and USDA rulemakings outlined in the Spring 2025 Unified Agenda may intersect with their current and planned product portfolios. Thoughtful stakeholder engagement – particularly during the anticipated comment periods – may help shape pragmatic implementation timelines and limit the risk of patchwork state requirements. Beveridge & Diamond is available to assist.

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