

2025 Food and Supplements Outlook: FDA Human Foods Program's Last Acts Before the New Administration

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Food and dietary supplement companies should be aware of a number of regulatory developments from the U.S. Food and Drug Administration (FDA or Agency) that could have significant impact as we enter the transition from the Biden Administration to the second Trump Administration. At this time, it is difficult to predict the scope and extent of FDA's food and dietary supplement policy changes, which will likely become clearer only after nominees for the Department of Health and Human Services (HHS) — including Robert F. Kennedy (RFK) Jr. for HHS Secretary and Martin Makary, M.D., for FDA Commissioner — are considered for confirmation. Any such policy shifts will come in addition to the adjustments already underway as FDA implements its October 2024 unified Human Foods Program (HFP), a reorganization of what was previously known as the Center for Food Safety and Applied Nutrition.

It is clear now that HFP has been tasked with publishing as many items on its agenda as possible before the change in administration. Starting at the end of 2024 and continuing into January 2025, HFP has been releasing a flurry of rulemakings, guidance documents, and other initiatives. While it is important to review these FDA publications and assess their effect on business and compliance, it is not known which of these new policy positions, if any, will remain after the transition. Typically, a new administration will give close scrutiny to all “midnight regulations.” As such, the Trump Administration may decide to revise or undo some agency actions via the Congressional Review Act and other tools.

The rise of the Make America Healthy Again (MAHA) movement — which, in part, seeks to address chronic diseases in America through food reforms — suggests that there may be a focus on significantly changing the food regulatory paradigm at HHS and FDA. We expect the new administration to continue HFP's focus on food safety, but beyond that, and depending on whether RFK is confirmed, the day-one priorities are unclear. Based on RFK's statements and the MAHA movement, ultraprocessed foods (UPFs) and food additives are likely to be a focus of the new administration.

Below are short summaries of significant recent developments regarding FDA's regulation of food and dietary supplements, including labeling issues and product safety considerations. We also include other recent developments: updates to the Coordinated Framework on biotechnology, increased public attention on UPFs, and a new interim process for Center for Veterinary Medicine (CVM) regulation of new animal food ingredients.

- **Front-of-Package Nutrition Labeling**: On January 14, HFP issued proposed rulemaking to require nutrition labels on the front-facing, principal display panel or bulk food labeling of most foods that already include Nutrition Facts labeling required under the Nutrition Labeling and Education Act of 1990. The proposed “Nutrition Info box” is intended to give consumers standardized information to allow for quick and easy comparison of nutrients while browsing products. Notably, FDA proposed exempting dietary supplements from the rule. The proposal also aims to amend nutrient content claim definitions for “low sodium” and “low saturated fat” claims “to align with current nutrition science” and ensure consistency in labeling, as recommended by a 2023 Reagan-Udall Foundation meeting on the topic. FDA has requested comments on several aspects of the proposed rule, including the size, format, and substance of the Nutrition Info box, the proposal to exempt dietary supplements, and nutrient content claim definitions.
- **Updated “Healthy” Nutrient Content Claim**: Just before the close of 2024, FDA finalized rulemaking updating the definition of “healthy” for food labeling, which includes dietary supplements. FDA’s focus of the claim is for individual foods, mixed products, main dishes, and meal products that meet food group equivalent (FGE) reference amounts. The Agency also allows dietary supplements to bear the claim if they meet applicable criteria. FDA also recognizes that vegetable, fruit, and protein powders produced from dried whole foods may be included in calculating applicable FGEs. Whether this new “Healthy” rule, with a February 25, 2028, compliance date, withstands the current change in administration will be based on an assessment of whether it aligns with the new administration’s priorities.
- **Labeling of Plant-Based Alternatives to Animal-Derived Foods**: Recognizing increased consumer demand for plant-based alternatives to animal products, such as eggs, seafood, poultry, meat, and dairy, FDA issued long-awaited draft guidance for industry to assist in labeling such non-standardized foods. In the draft guidance, FDA recommends “identifying the source of the plant-based ingredient(s) as part of the [product] name” rather than simply stating that the food is “plant-based.” For foods composed of a blend of different plant-based sources, FDA recommends naming the product using the “primary types of plant sources.” Much as with ingredient lists, “the predominant plant source by weight” should be listed first. It remains to be seen how this new guidance may be received, especially among those who have raised concerns about consumer confusion about the identity of products. This guidance does not address a related hot topic, the naming and labeling of “plant-based milk alternatives.”
- **Major Food Allergen Labeling Requirements**: FDA’s fifth edition of its major food allergen guidance finalizes the Agency’s updated thinking on allergen labeling requirements, addressing a whole host of timely topics, including sesame as a new major food allergen, allergen labeling for bulk foods, spice mixes, genetically engineered foods, and ingredients containing allergen proteins, as well as allergen statements for dietary supplements and labeling exemptions. The new guidance emphasizes that food labels must declare major allergens that are included as sub-ingredients or “incidental additives.”
- **FDA Guidance on Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens**: This final guidance outlines FDA’s approach to considering the public health importance of allergens beyond those included in the list of nine major food allergens, evaluated on FDA’s own initiative or in response to a citizen petition, in an effort to

establish regulatory requirements for new allergens. The guidance describes how interested persons should focus the scientific evidence surrounding non-listed food allergens around four factors, described as the evidence, prevalence, and severity of immunoglobulin E (IgE)-mediated food allergies coupled with the degree of allergenic potency that a substance has to cause an allergic reaction. FDA has also committed to evaluating other data, recognizing that some foods may cause both IgE- and non-IgE-mediated allergic reactions.

- **Action Levels for Lead in Processed Food for Babies and Young Children:** As part of FDA's 2021 *Closer to Zero* initiative to decrease contaminants, such as lead in foods over time, the Agency finalized guidance setting action levels for lead in processed foods intended for babies and young children. Recognizing that lead contaminants occur naturally and cannot be eliminated altogether, FDA aims to incentivize manufacturers to reduce lead levels in food. If lead levels rise above those specified in the guidance — 10 parts per billion (ppb) for fruits, vegetables, yogurts, custards/puddings, along with mixtures and single-ingredient meals (in agreement with USDA's Food Safety Inspection Service, which retains jurisdiction over meat and poultry products) and 20 ppb for single-ingredient root vegetables and dry infant cereals — the food may be considered adulterated and may be subject to enforcement action.
- **Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event:** This draft guidance focuses on what companies can do to prevent and mitigate potential contamination events. Examples include conducting root cause investigations that identify the scope of the problem and considering the use of whole genome sequencing, as well as adequately remediating the issue, including by performing sanitizing treatments.
- **Coordinated Framework Updates:** In these past few weeks, there have been changes affecting the U.S. agricultural and biotechnology sectors operating under the Coordinated Framework governing the interagency regulation of products relying on genetic engineering (GE). For example, FDA just finalized **Guidance for Industry 187B: Heritable Intentional Genomic Alterations in Animals: The Approval Process**, explaining how "its approval process applies in the context of products related to heritable intentional genomic alterations ("IGA") in animals," where those animals could be used in a variety of applications including food and medical products. The guidance stands at the intersection of FDA and USDA jurisdiction and has been the subject of discussion over which agency is better positioned to regulate — a topic that may be revisited during the second Trump Administration. Moreover, in a December 2, 2024, opinion in *National Family Farm Coalition v. Vilsack*, the U.S. District Court for the Northern District of California vacated the USDA Animal and Plant Health Inspection Service (APHIS) 2020 final SECURE rule (short for the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient rule) as arbitrary and capricious under the Administrative Procedure Act. The SECURE rule, issued during President Trump's first term, streamlined regulatory permitting processes for industry over the interstate movement of GE microorganisms and plants. As of now, APHIS has announced that it will revert to its pre-2020 approach to biotechnology regulation, including the *Am I Regulated?* process. It is unclear how this shift will play out, knowing that streamlining regulatory requirements for the biotechnology industry has been a consistent theme across the first Trump Administration and the Biden Administration (which issued the Executive Order 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy).

- **New Red. No 3. Restriction:** On January 15, FDA granted the Center for Science in the Public Interest's 2022 color additive petition and ordered that erythrosine (*i.e.*, Red No. 3) may no longer be used in regulated products. Manufacturers who use the ingredient in food, including dietary supplements, and ingested drugs will have until January 15, 2027 or January 18, 2028, respectively, to reformulate their products.
- **FDA-NIH Nutrition Regulatory Science Workshop, UPFs, and Dietary Guidelines:** Faced with public interest on healthy nutrition, in mid December 2024, HFP and the National Institutes of Health (NIH) held a two-day joint workshop with presentations from scientists and regulators who described data, questions, comments, and concerns about the proper way to regulate “ultra-processed foods” — a broad term, with no settled regulatory definition that includes snack and convenience foods, along with enriched products, plant-based alternatives to animal products, and infant formula. At the same time, the Dietary Guidelines Advisory Committee (DGAC) issued its **2025 Scientific Report** for public comment that includes a greater emphasis on plant-based diets and seafood consumption. It will be important to monitor whether and how these initiatives fit with the new administration's priorities.
- **Animal Food Ingredient Consultation (AFIC):** Key for the animal feed industry, CVM has released guidance announcing its new AFIC process to assess the safety of new animal food ingredients. Along with providing a baseline of safety information available about new ingredients, AFIC will also give FDA an opportunity to discuss any potential safety concerns with the manufacturer. FDA will maintain inventories of pending and completed AFICs on its website and will issue a “consultation complete” letter summarizing the information reviewed supporting its conclusions whether there are any questions about the safe use of the proposed ingredient. AFICs will be conducted as an interim process now that the 2007 Memorandum of Understanding (MOU) expired between FDA and the Association of American Feed Control Officials (AAFCO), where FDA previously agreed to provide technical review of animal food ingredient definitions requested by industry or AAFCO. During this time, the Agency is reassessing its animal Food Additive Petition and Generally Recognized as Safe Notification programs, both of which remain available for evaluating new animal food ingredients.

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