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"Healthy" Claims, Allergens, Heavy Metals, and More: FDA Acts on Food Safety and Nutrition Labeling Priorities in Biden Administration's Last Days

Gibson Dunn is prepared to help interested parties consider the implications of these policies and potential responses, including through regulatory counseling, FDA and legislative engagement, and litigation.

The U.S. Food and Drug Administration (FDA) has published a final rule and a number of draft and final guidance documents for foods in the final days of the Biden Administration. These documents advance or finalize initiatives in line with FDA's recent focus on food safety and nutrition labeling. If the documents are followed or finalized under the incoming Trump Administration, they will pose challenges to the food industry.

The regulatory developments include:

- **Final rule updating FDA regulations on "healthy" claims:** In December 2024, FDA published a final rule amending its regulations on "healthy" claims for foods, which it regulates as implied nutrient content claims.[1] The final rule is set to become effective on February 25, 2025, with a compliance date of February 25, 2028. The final rule provides that:
    - Certain nutrient-dense foods that are encouraged by the U.S. Department of Agriculture (USDA) *Dietary Guidelines for Americans, 2020-2025*, automatically

can bear “healthy” claims if they have no added ingredients except for water.[2] These include vegetables, fruits, fat-free or low-fat dairy, grains, and protein foods, such as lean meat, seafood, eggs, beans, peas, lentils, nuts, or seeds.[3]

- Other foods, including individual food products, mixed, products, main dishes, and meals may only bear “healthy” claims if they contain a minimum food group equivalent (FGE) amount of one or more nutrient-dense foods and fall within specific percentage Daily Value (DV) limits for added sugars, saturated fat, and sodium.[4] Foods may meet the new requirements based on per-50-gram nutrition information for foods with smaller reference amounts customarily consumed (RACCs).[5] As a result of the new standards, certain types of foods, including fortified breads, highly sweetened cereals and yogurts, and certain packaged foods cannot bear “healthy” claims under the final rule.[6] In establishing the requirements, FDA accepted some suggestions from industry comments, including incorporating vegetable and fruit powders produced by drying whole vegetables and fruits in FGE calculations, and raising certain limits for added sugars, saturated fat, and sodium, both of which allow more foods to be eligible for “healthy” claims.[7]
- Manufacturers of “healthy”-labeled foods must maintain records verifying compliance with FGE requirements, unless compliance can be sufficiently verified using the standard information required on the food label, for at least two years after introducing or delivering for introduction a food into interstate commerce.[8]

- **Final guidance updating FDA’s questions and answers (Q&A) guidance on allergen labeling:** In January 2025, FDA finalized the fifth edition of its Q&A guidance on food allergen labeling.[9] Among other changes, this guidance amends FDA’s historical interpretation of the major food allergens that are defined in Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (FDCA) and require labeling disclosures under Section 402(w).[10] Under the statute, milk, eggs, shellfish, tree nuts, wheat, peanuts, soybeans, and sesame, are “major food allergens.” FDA broadens its interpretation of certain of these categories, in particular “milk” (to include milk from goats, sheep, or other ruminants), “eggs,” (to include eggs from ducks, geese, quail, and other fowl), and “tree nuts” (to include those tree nuts for which a robust body of science supports classification as a major food allergen, and to omit certain previously-listed nuts, such as chestnuts, coconuts, and pili nuts). FDA also clarifies that incidental additives that are intentionally added to a food, such as wheat used in processing belts for rice crackers, are subject to allergen labeling requirements, even if not required to be in the ingredients list. FDA distinguishes incidental additives from substances that are unintentionally present due to cross-contact from shared equipment; the latter are not considered incidental additives and do not require declaration under either allergen labeling or ingredient listing requirements. The agency also clarifies that no FDA regulations specify conditions for “free” claims from major food allergens, and firms may include such claims on food labeling so long as they are truthful and non-misleading.
- **Final guidance outlining FDA’s approach to food allergens outside of major food allergens specified by statute:** FDA also finalized its guidance explaining how the agency evaluates the public health importance of food allergens other than the statutorily-specified major food allergens for regulatory purposes, including food labeling, food production, and the safety of substances added to food.[11] Most notably, the agency clarified that it considers data on both allergies that are mediated by immunoglobulin E antibodies (IgE)—which run the risk of anaphylaxis—as well as those that are not, such as celiac disease, in evaluating the public health importance of non-listed food allergens.

- **Final guidance establishing action levels for lead in processed foods intended for babies and young children:** FDA's *Closer to Zero* initiative[12] was launched in 2021 shortly after the issuance of a Congressional report on heavy metals in baby food.[13] FDA has stated that the initiative is intended to reduce dietary exposure to contaminants as low as possible while maintaining access to nutritious foods. In January 2025, FDA finalized a guidance document setting forth action levels for lead in processed foods intended for babies and young children.[14] The agency finalized action levels of 10 parts per billion (ppb) for fruits, vegetables other than single-ingredient root vegetables, mixtures, yogurts, custards/puddings, and single-ingredient meats, and 20 ppb for single-ingredient root vegetables and dry infant cereals. FDA reiterates that these action levels, while not binding, are intended to encourage manufacturers to limit lead exposure below these levels and may be used by FDA to determine whether to bring an enforcement action against a food it deems to be adulterated. In the final guidance, FDA has yielded to some industry concerns expressed in comments to the draft, including by focusing the document more explicitly on infants and children under two years old.

- **Draft guidance on labeling for plant-based alternatives to animal-derived foods:** FDA has published a draft guidance outlining the agency's approach to the naming and labeling of plant-based alternatives to eggs, seafood, poultry, meat, and dairy other than plant-based milk alternatives.[15] There, FDA states that plant-based alternatives are not standardized foods, and thus are not subject to established definitions or standards of identity. Moreover, FDA states that "[t]he fact that a standard of identity has been established for a food (under its common or usual name) or that a name is specified among the standard of identity regulations for a food does not preclude use of the name in the common or usual name of another food," though the use of that name must not be false or misleading. In particular, a plant-based alternative that uses either the name of a standardized food (e.g., "Soy-Based Cheddar Cheese") or a modified spelling (e.g., "Chik'N") should clearly qualify the plant source from which it is derived in the statement of identity and in the label (e.g., "Soy-Based Cheddar Cheese."). Foods derived from several plant sources should specify the primary types of plant sources used. FDA further notes that foods described as "plant-based" should also identify the plant source. FDA also recommends against labeling foods only as "vegan," "meat-free," or "animal-free" without disclosing the plant source in the standard of identity. Finally, FDA notes that manufacturers should ensure that any words or vignettes intended to convey a characterizing flavor (e.g., "artificially beef flavored") not be misleading as to the animal or plant source of the food. Comments on this draft guidance may be submitted by May 7, 2025.[16]

- **Draft guidance on sanitation programs for low-moisture ready-to-eat human foods:**FDA's newly launched Human Foods Program has identified microbiological food safety as one of the program's top FY 2025 deliverables. In line with this risk management focus, FDA has published a draft guidance on its food safety expectations for low-moisture ready-to-eat human foods, which include powdered infant formula, peanut butter, nut butters, powdered drink mixes, chocolate, powdered and paste medical foods, processed tree nuts, milk powders, powders spices, and various snack foods.[17] In the draft guidance, FDA states that cleaning techniques, including material flush techniques (also known as "product push" or "product purge"), are not sufficient on their own to mitigate pathogen contaminations on food contact surfaces for such foods. FDA also indicates that finished product testing is not sufficient to verify control of pathogens, and must be combined with other measures, such as production records, environmental testing, and microbiological testing at various points in the manufacturing process. The agency recommends extensive actions, including routine cleaning and sanitation breaks, use of whole genome sequencing in verification testing and root cause investigations, and

extensive verification of cleaning and sanitizing measures following a pathogen contamination event. Comments on this draft guidance may be submitted by May 7, 2025.[18]

Interested parties should take advantage of opportunities to comment on these documents and shape the agency's actions moving forward. Gibson Dunn is prepared to provide more detail on these developments to help interested parties consider their potential effects, submit comments, and prepare for potential challenges to agency actions.

[1] 89 Fed. Reg. 106064 (Dec. 27, 2024).

[2] *See* USDA, Dietary Guidelines for Americans, 2020-2025 (9th ed. 2020), available at: https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

[3] 89 Fed. Reg. at 106162-63.

[4] *Id.* at 106163-64.

[5] *See id.* at 106076-77.

[6] *See* FDA, "Use of the Term Healthy on Food Labeling," https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/use-term-healthy-food-labeling (last accessed Jan. 8, 2025).

[7] 89 Fed. Reg. at 106088-89, 106092-106101.

[8] *Id.* at 106164.

[9] FDA, Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5) (Jan. 2025), available at: https://www.fda.gov/media/117410/download.

[10] *See* 21 U.S.C. §§ 321(qq), 343(w).

[11] FDA, Guidance for FDA Staff and Interested Parties: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act (Jan. 2025), available at: https://www.fda.gov/media/157637/download.

[12] *See* FDA, "Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods," https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods (last accessed Jan. 8, 2025).

[13] Subcomm. on Econ. and Consumer Policy, Comm. on Oversight and Reform, U.S.H.R., "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury" (Feb. 4, 2021), available at: https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf.

[14] FDA, Guidance for Industry: Action Levels for Lead in Processed Food Intended for Babies and Young Children (Jan. 2025), available at: https://www.fda.gov/media/164684/download.

[15] FDA, Draft Guidance for Industry: Labeling of Plant-Based Alternatives to Animal-Derived Foods (Jan. 2025), available at: https://www.fda.gov/media/184810/download.

[16] *See* 90 Fed. Reg. 1139 (Jan. 7, 2025); Regulations.gov, Docket No. FDA-2022-D-1102, https://www.regulations.gov/docket/FDA-2022-D-1102 (last accessed Jan. 8, 2025).

[17] FDA, Draft Guidance for Industry: Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event (Jan. 2025), available at: https://www.fda.gov/media/184815/download.

[18] *See* 90 Fed. Reg. 1052 (Jan. 7, 2025); Regulations.gov, Docket No. FDA-2024-D-2604, https://www.regulations.gov/docket/FDA-2024-D-2604 (last accessed Jan. 8, 2025).

The following Gibson Dunn lawyers assisted in preparing this update: Katlin McKelvie, Gustav W. Eyler, Carlo Felizardo, and Wynne Leahy.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's FDA & Health Care practice group:

Gustav W. Eyler – Washington, D.C. (+1 202.955.8610, geyler@gibsondunn.com)
Katlin McKelvie – Washington, D.C. (+1 202.955.8526, kmckelvie@gibsondunn.com)
John D. W. Partridge – Denver (+1 303.298.5931, jpartridge@gibsondunn.com)
Jonathan M. Phillips – Washington, D.C. (+1 202.887.3546, jphillips@gibsondunn.com)
Carlo Felizardo – Washington, D.C. (+1 202.955.8278, cfelizardo@gibsondunn.com)
Wynne Leahy – Washington, D.C. (+1 202.777.9541, wleahy@gibsondunn.com)