The U.S. Food and Drug Administration (FDA) released a public inventory on July 12, 2023, of certain food ingredients that the agency has determined are unsafe because they are unapproved food additives that are not Generally Recognized as Safe (GRAS) when used as intended. FDA developed this inventory as part of its post-market surveillance of food ingredients. Notable ingredients included in the inventory are cannabidiol (CBD), melatonin, Delta-8-tetrahydrocannabinol (Delta-8-THC), and caffeinated alcoholic beverages. Concurrently, FDA also released lists of select chemicals in the food supply—including food ingredients, food contact substances, and contaminants (like short-chain PFAS, phthalates, and heavy metals)—under agency review.

How Does FDA Regulate Food Ingredients?

The Federal Food, Drug, and Cosmetic Act (FDCA) generally requires any substance reasonably expected to become a component of food under its intended conditions of use to be the subject of an applicable food additive regulation unless the substance is GRAS for its intended use, is the subject of a prior sanction or approval, or is otherwise exempt from regulation as a food additive. In the case of food contact substances, such substances may lawfully be used in accordance with an effective Food Contact Notification or a food additive regulation, or be the subject of a Threshold of Regulation exemption letter from FDA. Foods containing unauthorized food additives are considered "adulterated" under the FDCA and subject to FDA enforcement. Foods containing unauthorized ingredients may also be targets of private putative class action lawsuits as well as regulatory enforcement.

FDA's "Not GRAS" Public Inventory Unpacked

According to FDA's announcement, when the agency becomes aware of an ingredient for which there is no authorization as a food additive, the agency reviews the regulatory status of this ingredient, including whether the publicly available data and information show the use is safe and meets FDA's GRAS criteria for human food set out at 21 CFR Part 170. The agency's actions are intended to "protect public health, including enforcement actions and other post-market activities that warn manufacturers and the public of unsafe food additives and can result in the removal of unsafe products from the market." The inventory is not intended to be an exhaustive list of all unlawful food ingredients or all of the agency's post-market activities (i.e., warning letters, import alerts, seizures, and injunctions).

FDA explains that the agency conducts ongoing post-market compliance activities to identify conventional foods that contain substances for which there is no authorization as a food additive and then reviews the regulatory status of the substance(s). The agency's scientists analyze whether the intended use of the substance is GRAS or whether the substance is otherwise exempt from regulation as a food additive. If FDA scientists determine that a substance is an unapproved food additive because the substance is not GRAS for its intended use and is not otherwise exempt from regulation as a food additive, the scientists may document their post-market determinations in a memorandum. The new FDA database contains links to these memoranda as well as other agency actions and communications associated with the listed substances.

Among other substances, the agency highlighted several ingredients unapproved for use in conventional food, such as:

- CBD.
- Delta-8 THC.
- Partially Hydrogenated Oils (PHOs).
- Betel Nut (Areca catechu).
- 1,3-dimethylamylamine (1,3-DMAA.
- Melatonin.

In addition, FDA noted that caffeinated alcoholic beverages were not approved for use as conventional food products.

What Does This All Mean for Industry?

Food and beverage companies should review the newly released public inventory together with the new lists of chemicals under FDA review to assess whether their current product formulations or those in the pipeline contain any substances flagged by FDA.

FDA intends to ramp up its focus on post-market assessments of food ingredients and food contact substances. In this Q&A Session, Acting Director of FDA Office of Food Additive Safety Dr. Kristi Muldoon-Jacobs explains that the agency plans to take a more systematic and proactive approach to post-market assessments and is requesting new funding for its post-market review framework as part of President Biden's 2024 fiscal year budget.

In light of these developments, food and beverage companies should be prepared for a potential uptick in FDA enforcement activities, particularly against food ingredients and food contact substances FDA has flagged as unlawful or otherwise of concern. This increased visibility also sets the stage for potential scrutiny from consumer class action plaintiffs and state regulators.

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