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What Food and Beverage Manufacturers Should Be Considering With HHS Secretary Kennedy at the Reins

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Human Health and Services (HHS) Secretary Robert F. Kennedy Jr. has instructed the Food and Drug Administration (FDA) to revisit and consider rulemaking regarding its Generally Recognized as Safe (GRAS) notification and clearance scheme that enables food makers to add new ingredients to food products and, to some extent, dietary supplements.

It should be noted that HHS announced on Thursday, March 27th, a reduction in force of 10,000 employees, 3500 of which will be from the FDA. The announcement says that food, drug, and device reviewers as well as inspectors will NOT be among the force reductions.

How the GRAS regulatory program works:

If a food manufacturer adds a new ingredient to their food products, the ingredient is subject to an FDA premarket review and approval. This process is costly in time, effort, and money. However, under the FDA's regulatory scheme, manufacturers can avoid this type of application if qualified food experts generally recognize the food ingredient as safe under the conditions of its intended use (GRAS). A manufacturer can make a GRAS Notification submission to the FDA to have it review scientific testing and related regulatory information establishing its safe use as well as reviews by the food expert panel of the information, and if after FDA's own review of the same, the Agency concurs, it will issue a "No Objection" letter. This is not an approval mechanism, but more of a clearance process and operates much like an approval. Over time, the FDA has completed more than 1,000 GRAS reviews and on average, evaluates around 75 per year. Nevertheless, under the current application of the law and implementing regulations, the manufacturer is not obligated to file a GRAS Notification submission with FDA, but it may go to market "at risk" with the food containing the new additive thus utilizing a "self-affirmation" of the new food ingredient in lieu of either an expensive food additive approval or a GRAS ingredient No Objection review and clearance.

What Is Happening Now?

On March 10, HHS Secretary Kennedy directed the FDA to eliminate the pathway for companies to self-affirm that food ingredients are safe. FDA actions to mandate GRAS Notifications will require notice and comment rulemaking, which is not a fast process and may include public meetings and other opportunities for engagement prior to issuing a proposed rule. Congress may get involved by pursuing legislative changes to the Federal Food, Drug, and Cosmetic Act (FDCA) regarding the regulatory review of food ingredients.

The change from voluntary to mandatory GRAS notifications will have a significant impact on the affected food manufacturing companies. They, therefore, should engage the FDA on multiple levels regarding this initiative (at a minimum comment to any proposed rule) as even GRAS notification submissions, while not as extensive, expensive, or time-consuming as food additive petitions, involve substantial time, effort, and expense.

Considerations for food manufacturers:

- Would the FDA grandfather ingredients already considered GRAS in foods and beverages currently on the market, and how will they do so?

- Will a gradual phase-in period be applied by the FDA for mandatory GRAS Notifications to be submitted to the Agency?
- Will the Agency require more rigorous and more complex data and information in a mandatory GRAS Notification than it currently requires?
- With current DOGE downsizing recommendations, will the FDA be able to review the mandatory GRAS notifications in a reasonable time frame?
- Will user fees for mandatory GRAS Notifications be employed by the Agency?

The premarket review aspects of this change to a mandatory GRAS notification process will very likely increase the time before new food product innovations may be introduced to the commercial marketplace and it will very likely increase the enforcement actions taken by the FDA as well.

The FDA may look to the EU to compare food ingredients that are banned in Europe but are still permitted here. Some substances that have been mentioned as possible candidates to be scrutinized going forward are:

- Titanium dioxide, a whitening agent added to products like skim milk;
- Brominated vegetable oil, added to citrus drinks like Mountain Dew;
- Potassium bromate, an additive used to strengthen bread dough;
- rBST, a hormone to increase milk production in cows;
- Artificial trans fats, used to make liquid vegetable oil more solid and shelf stable; and
- Many synthetic dyes, used as food coloring.

No Announced Timeline

While the FDA has been directed by HHS Secretary Kennedy to explore this rulemaking, there is no announced timeline for a proposed mandatory GRAS Notification rule at this time. While the proposal is in its early stages, companies in the conventional food and beverage industries should seriously consider engaging in the forthcoming notice and comment regulatory process.

If you have questions or would like to submit comments with the assistance of counsel once the notice comment rulemaking process begins, please reach out to Mark Yacura or any of our Baker Donelson attorneys in the Firm's FDA Regulatory and Compliance Group, and we can assist you.