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Re: Docket Number FDA-2025-P-3071

Dear Dr. Kessler: This letter is in response to your August 6, 2025, citizen petition (FDA-2025-P-3071), to the Food and Drug Administration (FDA), received on August 11, 2025, in which you ask FDA, among other things, to revoke the Generally Recognized as Safe (GRAS) designation for certain refined carbohydrates as a way of lowering Americans' health risks due to poor diets based on the likelihood that they contribute to metabolic harm, and to work with the food industry to reduce the use of processed refined carbohydrates as rapidly as possible.

As you know, your petition raises complex public health and societal issues that impact everyday American life and require fulsome debate, consideration, and action by and among consumers, stakeholders, industry, and the whole of government. The numbers tell the tale: Obesity rates among Americans have tripled over the past 30 years.¹ Heart disease kills more Americans than any other condition, and one in 20 Americans have some form of cardiovascular disease.² Thirty-eight million Americans, or 12% of the population, have type-2 diabetes,³ with youth rates soaring.⁴ Over 2 million cancer cases were diagnosed in 2025, and over 600,000 Americans died from cancer.⁵ 77% percent of American youth are ineligible for military service, with obesity and other diet-related conditions as significant factors.⁶ The 20% of Americans who live in rural areas have even higher rates of obesity and diabetes than their urban and suburban counterparts, and are more likely to die of heart disease, cancer, and stroke.⁷ The science is clear that these skyrocketing rates of chronic disease are tied to the Standard American Diet, particularly the proliferation of ultra-processed food.

In addition to the harrowing human cost, the chronic disease crisis is causing significant financial harm to the country. Indeed, the United States spends \$5 trillion per year on health care. Ninety percent of those expenditures are on patients with chronic disease, an amount that exceeds the economic output of the entire U.S. food system, four times over.⁸ Since almost half of health care spending in the United States is by the Federal government, the impact on American taxpayers and the Federal deficit is obvious.⁹ The effects on American children are even more tragic. To quote from the Administration's MAHA Report: "Today's children are the sickest

generation in American history in terms of chronic disease and these preventable trends continue to worsen each year, posing a threat to our nation's health, economy, and military."¹⁰

Your petition focusses on the dramatic growth of refined starches and sweeteners in the U.S. food system – core ingredients associated with ultra-processed food.

Under current statute and regulation, food companies are required to ensure the safety of the ingredients they are using in the quantity they are adding them to food. I will be calling on companies to provide any safety information they have to HHS on the health impacts of refined starches and sweeteners to allow FDA to evaluate the GRAS status of the refined starches and sweeteners listed in your petition.

I have included more details below, and outlined additional steps the Trump Administration is taking the reverse the chronic disease crisis.

GRAS Status of Refined Starches and Refined Sugars

Your petition argues that the listed ingredients are no longer Generally Recognized as Safe (GRAS), and thus manufacturers using those ingredients should come forward with evidence of their safety, or reformulate their products without them. When FDA last conducted a comprehensive review of the many sweeteners used in modern food processing, it reached conclusions affirming GRAS status over 40 years ago, using data that was often derived from the 1970s or even earlier. It is indeed true that there has been a flood of new scientific data in the interceding years that paint a different picture. Today, there is strong, consistent evidence linking regular consumption of added sugars, especially in beverages, to a high risk of type 2 diabetes. Moreover, excess sugar is known to contribute to weight gain and obesity, as well as a number of metabolic effects (e.g., increase in liver fat, worsened insulin resistance, and raised triglycerides). And for effects on the heart, many cardiovascular experts now believe the evidence supports a conclusion that refined carbohydrates may actually threaten heart health more than fats.¹¹ Accordingly, the new Dietary Guidelines for Americans have recommended that consumers limit their sugar and refined carbohydrate consumption as part of a healthy diet, and, to the extent possible, added sugars be avoided entirely by our youth. In reaching its GRAS conclusions in the 1980s, the agency committed to reevaluating the safety of sugars if dietary consumption increased significantly.¹² Your petition is further evidence that the time has come.

Next Steps on Petition

For the reasons stated, I believe your petition points toward an historic opportunity to significantly improve the quality of our food supply and thus the health of our citizens.

FDA's statute and regulations require that GRAS status be based on the ingredient's intended use. We want to see any information that proves these ingredients at the quantities they are being added to the food supply should still be generally considered safe. Today, HHS will begin seeking any detailed safety studies food companies may have conducted for proving the safety of the refined starches and refined sugars they are adding into the food supply.

Additional Administration Steps

The Trump Administration is working across government to accomplish your petition's goals of improving nutritional outcomes, lowering chronic disease rates, addressing concerns surrounding ultra-processed foods, and removing ingredients and additives from the American food supply that fuel our chronic disease crisis and are not safe. Thus, during my time as Secretary, I intend to work across the Administration to oversee a process that will include at least the following actions:

1) Fully Implementing the new Dietary Guidelines for Americans.

Our citizens need and deserve new guidance on how to build healthier diets. The Administration's new Dietary Guidelines for Americans provide the public with direction on a better way forward, with an emphasis on consumption of whole foods—including protein, healthy fats, dairy, fruits and vegetables, and whole grains—and minimization of ultra-processed foods; primarily those made with ingredients of the kind noted in your petition such as refined carbohydrates, added sugars, and sodium. HHS is working in lockstep with USDA and other governmental partners to implement the Dietary Guidelines for Americans across federal procurement programs and in nutritional standards that impact schools, military bases, veterans' centers and hospitals, and other local, state, and federal programs. We will use data from the Dietary Guidelines for Americans to develop guidance, public campaigns, and medical education programs to focus diets on wholesome real foods and empower consumers to make informed choices. Similarly, under the recently created joint FDA and National Institutes of Health Nutrition Regulatory Science Program, a broader research agenda is being designed to further strengthen the science and better understand questions such as the mechanisms by which ultra-processed foods adversely affect health, and how these foods might affect satiety hormones, appetite regulation, and energy homeostasis compared to whole and minimally processed food.

2) Engaging Congress, the States, the Food Industry, and the Public in a Strategy to Address the Concerns Raised by Ultra-Processed Foods.

It will be critical to foster a national dialogue on the issues identified in your petition, the MAHA Report, and the Dietary Guidelines for Americans, as we work toward effectuating solutions. With the considerable urgings of a growing and active community of stakeholders focused on

nutrition and diet-related chronic disease, there is already bipartisan interest in both the United States Senate and House of Representatives to tackle these issues, with reform of FDA's GRAS standards and chemical safety processes at the forefront of their efforts. States have likewise been increasingly active in devising state-level solutions—in the face of federal inaction—and I have long encouraged and supported their efforts to focus on the problem as a mechanism to drive federal change.

3) Ongoing and Systematic Reassessment of Ingredients and Additives of Concern.

As your petition notes, many food ingredients were given a GRAS status decades ago, and scientific knowledge of their metabolic and other health effects have evolved over time. Food chemical safety is one of FDA's primary focus areas, which aligns with this Administration's efforts to Make America Healthy Again through protecting the food supply from unsafe chemicals and additives. Post-market safety reviews are a key part of this larger strategy and are well underway at FDA. During my tenure as Secretary, FDA has already developed a new systematic post-market review process for chemicals in foods, including building out a dedicated office to proactively facilitate and expedite post-market reviews of food additives for the first time in FDA history. Additionally, FDA has expanded the list of chemicals currently under agency review to include additives such as butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and azodicarbonamide (ADA), and has taken steps to expedite other reviews underway, like those for phthalates and propylparaben. Any reviews that conclude that earlier GRAS determinations may have been made in error, or may no longer meet contemporary scientific standards for safety, will result in the initiation of a process to reevaluate GRAS status. In 2026, FDA will also finalize a prioritization tool that determines the rankings of chemicals the agency will prioritize for reassessment, provide the public with information about FDA's systematic post-market assessment process, and continue to advance the efforts to facilitate the transition from petroleum-based dyes to natural alternatives.

4) Added Sugar Reduction Strategy.

Many of the refined carbohydrates included in your petition are sweeteners or ordinary table sugar combined with various additives. As noted, evidence of the health risks of over consumption of sugar is clear and overwhelming, as is the contribution that certain ultra-processed foods make toward excess sugar consumption in the United States. In the new Dietary Guidelines for Americans, we focus on this problem, and to support the Guidelines, I have directed FDA to develop an added sugar reduction strategy that will encourage food manufacturers, retailers, and restaurants to reduce added sugars in their products and provide greater transparency to consumers on added sugar content. On January 23, 2026, FDA's Human

Foods Program released its 2026 priority deliverables, which include specifics on this strategy.
(Add citation)

5) Labeling to Better Inform Consumers.

I believe consumers need to have as much information as possible to make good dietary decisions, especially with regard to ingredients and nutrients about which experts may have health concerns. Therefore, as directed by the Administration's MAHA Report, HHS and FDA will develop a plan for improved nutrition and ingredient labeling, including taking steps toward finalizing a potential front-of-pack labeling scheme that will complement existing nutrition labeling. I believe front-of-pack labeling will ultimately provide consumers with greater transparency and additional context to help them quickly and more easily identify foods that can help them build a healthy eating pattern and avoid those that don't.

6) Facilitate Research and Technical Assistance to Industry.

As your petition notes, the evolution of ultra-processed foods occurred partly due to the ready availability and low cost of many of the ingredients that characterize such foods. While industry has awoken to the growing consumer momentum around ultra-processed foods and is quickly reformulating products to meet the moment, we must take steps to assist food processing companies in identifying ways to reformulate their products to be healthier, safer, and cost-efficient, especially for the more than 50% of food manufacturers that are small businesses. I stand ready to work alongside any food company that wishes to engage.

I am also directing FDA to work with our colleagues at USDA on a potential research agenda that can coordinate with and complement industry efforts to find healthier substitute ingredients, as well as healthier manufacturing and agricultural practices. We know that ultra-processed foods constitute around 70% of the food supply in the United States, and the vast majority of American households rely on ultra-processed foods for some or all of their daily diet. Industry can and should reformulate, and the federal government is committed to partnering with industry to do so in a healthful, economically, and sustainable way.

[conclusion below; to be worked on]

This Administration is leading a thoughtful, methodical, and scientifically sound approach to improving the U.S. food supply and driving down diet-related chronic disease rates to benefit ALL Americans. In this instance, while change can be difficult, it is an absolute necessity in order to safeguard our collective future. This Administration is committed to doing the work...

Signed

Robert F. Kennedy, Jr.

Secretary

¹ CDC. 2013. Obesity—United States, 1999-2010. Morbidity and Mortality Weekly Report. 62(03); 120-128. [Obesity — United States, 1999–2010](#)

² CDC. Heart Disease Facts. [Heart Disease Facts | Heart Disease | CDC](#)

³ American Diabetes Association. Statistics about Diabetes. [Diabetes in America: Prevalence, Statistics, and Economic Impact](#)

⁴ CDC. National Diabetes Statistics Report. [National Diabetes Statistics Report | Diabetes | CDC](#)

⁵ American Cancer Society. Cancer Facts & Figures 2026. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2026-cancer-facts-figures.html>

⁶ Council for a Strong America. [77 Percent of American Youth Can't Qualify for Military Service • Council for a Strong America](#)

⁷ NIH. News in Health. Health in Rural America. [Health in Rural America | NIH News in Health](#)

⁸ Tufts University Food is Medicine Institute. 2023. [Tufts-Food-is-Medicine-Institute 2023-FIM-Fact-Sheet.pdf](#)

⁹ American Medical Association. 2025. Trends in health care spending. [Trends in health care spending | Healthcare costs in the US | AMA](#)

¹⁰ The MAHA Report. 2025. <https://www.whitehouse.gov/maha/>

¹¹ Moyer, Melinda Wenner. 2010. Carbs Against Cardio: More Evidence that Refined Carbohydrates, not Fats, Threaten the Heart. Scientific American. [Carbs against Cardio: More Evidence that Refined Carbohydrates, not Fats, Threaten the Heart | Scientific American](#)

¹² 53 Fed. Reg. 44862, 44863 (Nov. 7, 1988).