U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Thais Magalhaes
Tate & Lyle Solutions USA LLC d/b/a CP Kelco U.S., Inc
3100 Cumberland Blvd., Suite 600
Atlanta, GA30339

Re: GRAS Notice No. GRN 000943

Dear Ms. Magalhaes:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement to GRN 000943. We received CP Kelco U.S., Inc. (CPK)'s supplement on August 28, 2025. The supplement addresses changes to the manufacturing method and specifications. CPK submitted clarifying information on January 30, May 4, 2026, and June 21, 2026, on the submitting entity, manufacturing method, and specifications.

We previously responded to GRN 000943 on April 9, 2021. We stated that we had no questions at that time regarding CPK's conclusion that citrus fiber is GRAS for use as an ingredient, binder, gelling aid, thickening aid, bulking aid, emulsion stabilizer, or cloud stabilizer in baked goods and baking mixes; alcoholic beverages (cocktail drinks); beverage and beverage bases (sport or electrolyte drinks, fluid replacement drinks, non-milk-based meal replacement beverages, protein drinks); breakfast cereals (excluding instant); cheeses; specialty coffee drinks and ready-to-drink tea beverages; ketchup and relish; confections and frostings (excluding raw sugars); dairy product analogs; egg substitutes; fats and oils (fat-based sauces, salad dressings, margarine and margarine-like spreads, mayonnaise and mayonnaise-type dressings); fish products (excluding catfish); frozen dairy desserts; fruit and water ices; gelatins, puddings, and fillings; grain products and pastas; gravies and sauces; jams and jellies; milk products; nuts and nut products; plant protein products; processed fruits and fruit juices; processed vegetables and vegetable juices; soft candy; soups and soup mixes; and sweet sauces, toppings, and syrups at levels up to 3%, excluding use in infant formula, products that are under the jurisdiction of the U.S. Department of Agriculture.

Additionally, we responded on July 26, 2022 to a supplement dated June 3, 2022. We stated that we had no questions at that time regarding CPK's conclusion that citrus fiber is GRAS for use as a binder in beef hot dogs and turkey sausages at levels up to 3.5% and in other processed meat and poultry products at levels up to 3%, and as an ingredient, binder, gelling aid, thickening aid, bulking aid, emulsion stabilizer, or cloud stabilizer in baked goods and baking mixes at levels up to 5%, non-milk-based meal replacement beverages and protein drinks at levels up to 3%, and ready-to-eat breakfast cereals at levels up to 6%.

In this supplement dated August 28, 2025, CPK informs us of its view that citrus fiber is GRAS, through scientific procedures, for the same intended uses as described in GRN 000943 and the June 3, 2022 supplement, excluding use in infant formula and food products under the jurisdiction of the U.S. Department of Agriculture.

In this supplement, CPK describes the changes to the manufacturing method and specifications for citrus fiber. CPK states that the modified manufacturing process does not include the acidification and neutralization steps and, therefore, does not involve the use of sulfuric acid, potassium hydroxide, and sodium hydroxide. Instead, the chopped and optionally pre-washed citrus peels are washed three times using 40%, 50-55%, and 60-65% ethanol. During the washing steps, the citrus peels undergo heat treatment and defibrillation by applying mechanical energy. The washed material is then separated using a solid-liquid mechanical separation. The solid fraction is subsequently chopped, dried, and milled to produce the final citrus fiber, as described in GRN 000943. CPK states that citrus fiber is manufactured under current good manufacturing practices and that all raw materials and processing aids are food grade and are used in accordance with applicable U.S. regulations or are GRAS for their intended use.

CPK states that the changes to the specifications for citrus fiber include fiber content (from >80% to >70%), pH (from 3.0–5.0 to 3.2–5.5), particle size (from <3% to <5% on a 0.25 mm test sieve), and water holding capacity (from 15–35 to >6 g/g). Additionally, CPK updates the specifications for arsenic from ≤0.5 mg/kg to ≤0.3 mg/kg) and adds specifications for cadmium (≤0.3 mg/kg) and mercury (≤0.5 mg/kg). CPK provides the results from three non-consecutive batch analyses to demonstrate that citrus fiber can be manufactured to meet these specifications.

CPK states that an updated literature search was performed and did not identify any studies that would impact the safety of the ingredient for its intended use.

Based on the available data and information, CPK concludes that citrus fiber is GRAS under the intended conditions of use.

Standards of Identity

In the notice, CPK states its intention to use citrus fiber in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, & Cosmetic (FD&C) Act, a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products

containing citrus fiber bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. The Office of Pre-Market Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of CPK 's notice concluding that citrus fiber is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing citrus fiber. Accordingly, our response should not be construed to be a statement that foods containing citrus fiber, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that CPK provided, as well as other information available to FDA, we have no questions at this time regarding CPK's conclusion that citrus fiber is GRAS under its intended conditions of use. This letter is not an affirmation that citrus fiber is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 000943 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

Digitally signed by SUSAN J. CARLSON -S
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Director
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