U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Loula Merkel
Comet Biorefining Corporation
1051 Perimeter Drive, Unit 1150
Schaumburg, IL 60173

Re: GRAS Notice No. GRN 001266

Dear Ms. Merkel:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001266. We received Comet Biorefining Corporation (Comet)'s notice on March 27, 2025, and filed it on July 9, 2025. Comet submitted amendments to the notice on November 21, 2025, January 20, 2026, and February 11, 2026, that provided additional information about the composition, specifications, intended uses, dietary exposure, and safety narrative.

The subject of the notice is wheat fiber extract for use as a source of dietary fiber in the food categories and at the maximum use levels as specified in Table 1 (excluding use in infant formula, foods for infants, products under the jurisdiction of the United States Department of Agriculture). The notice informs us of Comet's view that these uses of wheat fiber extract are GRAS through scientific procedures.

Table 1. Intended uses of wheat fiber extract.

Food category	**Food uses**	**Maximum use level (%)**
Baked goods and baking mixes	Brownies	12.5
	Muffins	4.5
Beverages and beverage bases	"Energy" drinks and sports drinks	1.4
	Non-milk-based meal replacement, protein and nutritional beverages (including powders)	2.1
	Carbonated or flavored water	1.4
Breakfast cereals	Ready-to-eat (RTE) breakfast cereals (puffed)	33.3
	RTE breakfast cereals (biscuit-type)	8.3
	RTE breakfast cereals (high-fiber)	12.5
Coffee and Tea	Coffee (instant, brewed, iced/hot)	1.0

Food category	Food uses	Maximum use level (%)
	Bottled/canned coffee	1.8
	Tea (instant, brewed, iced/hot)	1.4
	Bottled/canned tea	1.8
Grain products and pastas	Cereal and granola bars	12.5
	Nutrition and protein bars, and meal replacement bars	12.5
Milk products	Flavored milk, milk drinks, milk shakes, and mixes	2.1
	Milk-based meal replacement, nutrition, and protein beverages	2.1
	Yogurt drinks	5.6
Processed fruits and fruit juices	Fruit juices	2.1
	Fruit-flavored drinks and mixes (including lemonade)	2.1
Processed vegetables and vegetable juices	Vegetable juices	2.1
Snack foods	Extruded savory snacks	16.7
Soft candy	Chocolate products and soft candy (including soft fruit leather, fudge, marshmallows, and dietetic candies)	16.7

Our use of the term, "wheat fiber extract" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence (NCE). The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for "wheat fiber extract."

Comet describes wheat fiber extract as a brown powder derived from the straws of the wheat (*Triticum aestivum*) plant through a hydrothermal extraction process. Comet states that wheat fiber extract is composed primarily of xylo-oligosaccharides, arabinoxylan, and arabinoxylo-oligosaccharides, which consist of linear backbones of β-(1,4)-linked D-xylopyranosyl (xylose) units with arabinose substitutions in arabinoxylan. Comet states that the degree of polymerization (DP) of wheat fiber extract

varies between 3 to 30 (average DP of 25), with over 80% falling within this range. The remaining portion of wheat fiber extract has a DP > 30. The range of DP for the polymers in wheat fiber extract results in the number-average molecular weight (Mn) of approximately 3.5 kDa and the weight-average molecular weight (Mw) of approximately 4.2 kDa. Other components of wheat fiber extract include starch (<10% dry matter basis (DM)), ash (<5%), protein (<8%), lignin (approximately 15% DM), and free mono- and disaccharides (<5% DM).

Comet describes the method of manufacture for wheat fiber extract. Wheat straws are first reduced in size using a shredder and hammer mill. The size-reduced straws are then treated with steam at an elevated temperature of ~200 °C and pressure of up to 20 bar for ~10 minutes to allow the hemicellulose fraction to become water-soluble. The steam-treated wheat straws are agitated in water and the solids are removed. The pH of the liquid portion is adjusted using sodium (or potassium or calcium) hydroxide and purified using membrane filters. The resulting liquid stream is evaporated and/or spray-dried to produce the final wheat fiber extract. Comet states that wheat fiber extract is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food-grade and are used in accordance with appropriate U.S. regulations.

Comet provides specifications for wheat fiber extract that include a minimum level of total dietary fiber (> 65% DM)[1], ash (<5 %), moisture (<8%), lead (< 0.1 mg/kg), mercury (< 0.05 mg/kg), arsenic (<0.1 mg/kg), cadmium (<0.3 mg/kg), and microorganisms, including *Salmonella* serovars (absent in 25 g). Comet provides the results from the analyses of five non-consecutive batches to demonstrate that wheat fiber extract can be manufactured to meet these specifications. Comet provides the results of a stability study and states that the wheat fiber extract remains stable for two years when stored at 25°C and 60% relative humidity.

Based on food consumption data from the 2017-2018 National Health and Examination Survey (NHANES), Comet estimates the eaters-only dietary exposure to wheat fiber extract from the intended uses for the U.S. population aged 2 years and older to be 14 g/person (p)/d (0.23 g/kg body weight (bw)/d) at the mean and 27 g/p/d (0.45 g/kg bw/d) at the 90th percentile. Comet notes that their intended uses of wheat fiber extract will substitute for other sources of dietary fiber ingredients, and therefore, there will be no increase in the cumulative dietary exposure to dietary fiber from the intended uses of wheat fiber extract.

Comet states that the identity and composition of wheat fiber extract, including the arabinoxylan and xylooligosaccharide profiles, is comparable to other dietary fiber ingredients, including wheat bran extract evaluated in GRN 000343[2], corn bran

[1] Total dietary fiber of >65% DM is based on the sum of the AOAC 2009.01 method and the method for lignin determination.

[2] The subject of GRN 000343 is wheat bran extract composed primarily of xylo- and arabinoxylo-oligosaccharides. We evaluated this notice and responded in a letter dated November 22, 2010, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

arabinoxylan evaluated in GRN 001073[3], and xylooligosaccharides evaluated in GRN 000458[4] and GRN 000816[5]. Comet also states that dietary fiber components in wheat fiber extract are expected to have the same metabolic fate in the human body as other plant-derived dietary fibers, including those that have been determined to be safe for human consumption. Comet conducted a literature search through September 2025, and did not identify any information that would contradict its GRAS conclusion.

Comet references published toxicological studies demonstrating the safety profile of arabinoxylan, arabinoxylan-oligosaccharides, and xylooligosaccharides. Comet discusses acute toxicity studies on arabinoxylan and xylooligosacharides, subchronic studies on wheat bran extract (80% arabinoxylan-oligosaccharides), and repeated dose studies on xylooligosaccharides. No treatment-related adverse effects were reported in the studies, except for one subchronic study on xylooligosaccharides in beagles that reported transient diarrhea and vomiting in the highest dose group tested, which resolved during the recovery period. Studies on wheat bran extract and xylooligosaccharides reported no mutagenic or genotoxic activity. Comet also discusses published human studies on a different wheat fiber extract, arabinoxylan-oligosaccharides, and related oligosaccharides, noting no treatment-related adverse effects. Comet acknowledges that no direct toxicological studies have been conducted on their wheat fiber extract; however, they state that the weight of evidence from safety studies on comparable dietary fiber ingredients supports the safe use of wheat fiber extract. Comet concludes that potential contaminants for wheat fiber extract do not pose safety concerns.

Based on the totality of information discussed in the notice, Comet concludes that wheat fiber extract is GRAS under the conditions of its intended use.

Standards of identity

In the notice, Comet states its intention to use wheat fiber extract 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, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C

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[3] The subject of GRN 001073 is corn bran arabinoxylan. We evaluated this notice and responded in a letter dated March 21, 2021, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

[4] The subject of GRN 000458 is xylooligosaccharides. We evaluated this notice and responded in a letter dated August 23, 2013, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

[5] The subject of GRN 000816 is xylooligosaccharides from sugarcane. We evaluated this notice and responded in a letter dated April 29, 2019, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

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 wheat fiber extract 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 ONFL in NCE. OPMAS 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.[6]

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additive. In the notice, Comet describes wheat fiber extract as a brown powder. As such, the use of wheat fiber extract in food products may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring. Our response to GRN 001266 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Food Ingredients in OPMAS.

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 Comet's notice concluding that wheat fiber extract 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 wheat fiber extract. Accordingly, our response should not be construed to be a statement that foods containing wheat fiber extract, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

[6] The definition of "dietary fiber" in 21 CFR 101.9(c)(6)(i) was added by FDA's final rule revising the nutrition and supplement facts labels (81 FR 33742, May 27, 2016). This final rule, among other things, defines dietary fiber as non-digestible soluble and insoluble carbohydrates (with three or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with three or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

Based on the information that Comet provided, as well as other information available to FDA, we have no questions at this time regarding Comet's conclusion that wheat fiber extract is GRAS under its intended conditions of use. This letter is not an affirmation that wheat fiber extract 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 001266 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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