U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Stella Si
Anchor Center for Certification
No. 1295 Chuan Qiao Road, Building 2, Suite 302
Shanghai, 201206
CHINA

Re: GRAS Notice No. GRN 001255

Dear Ms. Si:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001255. We received the notice that you submitted on behalf of MoreMeat (Guangzhou) Biotech Co., Ltd (MoreMeat) on February 24, 2025, and filed it on May 15, 2025. MoreMeat submitted amendments to the notice on July 25, 2025 and August 27, 2025 that clarified the manufacturing process, specifications, stability, intended uses and safety information.

The subject of the notice is mycelial biomass of *Fusarium compactum* CGMCC 41312 (fungal protein) for use as an ingredient and a source of protein in the foods and at the maximum use levels as specified in Table 1, excluding use in infant formula and products under the jurisdiction of the United States Department of Agriculture. The notice informs us of MoreMeat's view that these uses of fungal protein are GRAS through scientific procedures.

Table 1. Proposed uses and use levels for *F. compactum* CGMCC 41312 fungal protein.

Food Category	Food Uses	Maximum use level (%)
Baked Goods	Breads, rolls, bagels, muffins, biscuits, cornbread, tortillas, cakes, cookies, pies, pastries, doughnuts, crackers, pancakes, waffles	50
Dairy Analogs	Non-dairy milk (soy, almond, rice, oat, coconut), coffee creamers, imitation cheese, nutritional drinks and shakes	50
Non-dairy Yogurt	Coconut milk yogurt, almond milk yogurt	70
Fats and Oils, Condiments	Cheese sauce, fish sauce, gravies, soy-based sauces, condiments (ketchup, mustard, hot	30

Food Category	Food Uses	Maximum use level (%)
and Sauces	sauce), salad dressings, mayonnaise	
Grain Products	Pasta (regular, vegetable, whole grain, gluten-free), noodles (chow mein, rice noodles)	50
Meat and Egg Analogs	Imitation crab, egg substitutes, soybean curd, meat analogs (bacon, chicken, hot dogs, burgers)	90
Processed Fruit Juices	Fruit smoothies (with/without dairy), high protein juices	60
Processed Vegetable Juices	Tomato juice cocktail, mixed vegetable juice, vegetable smoothies	60
Protein Powders	Protein powder mixes	90
Soups and Soup Mixes	Canned soups	60
Frozen or Shelf Stable Prepared Meals	Frozen dinners, pizza, pasta dishes, turnovers, shelf stable prepared meals	60

Our use of the terms "fungal protein" and "mycelial biomass of *F. compactum* CGMCC 41312" 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 non-standardized 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. The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for "fungal protein."

MoreMeat provides information on the identity and composition of fungal protein, describing it as an off-white to light yellow, dough-like matter containing ≥43% protein (on a dry weight basis (d/w)), carbohydrates, fat, ash, and moisture. MoreMeat states that under well-controlled cultivation conditions, *F. compactum* CGMCC 41312 grows into a filamentous mat of biomass with a texture profile similar to that of muscle fibers. MoreMeat indicates that *F. compactum* CGMCC 41312 was isolated from soil in Shennongjia, Hubei Province, China. MoreMeat

states that the production microorganism is non-genetically engineered and has been deposited in the China General Microbiological Culture Collection Center (CGMCC) with the designation number 41312.

MoreMeat states that after fermentation, the biomass is heat treated to inactivate enzymes and ensure that no live *F. compactum* CGMCC 41312 is present in the final product. After heat treatment, the fermentation broth is filtered using a vacuum drum filter to remove excess water and cool the product. The residues of the raw materials are removed during this filtration process. Fungal protein is then packed in an aluminum foil bag and vacuum sealed. MoreMeat states that fungal protein is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food grade and approved for their respective uses in accordance with an appropriate U.S. regulation, are GRAS for their intended use, or are the subject of an effective food contact notification. MoreMeat states that none of the raw materials are derived from major allergens and fungal protein does not contain major allergens.

MoreMeat provides specifications for fungal protein that includes protein content (≥43% d/w), total fiber (≥25% d/w), ash (<5% d/w), moisture (≤78% w/w), ribonucleic acid (≤2% d/w), and limits for heavy metals, including lead (<0.1 mg/kg) and microorganisms such as *Salmonella* spp. (not detected in 25 g), *Listeria monocytogenes* (not detected in 25 g), *Escherichia coli* (not detected in 1 g), and *Staphylococcus aureus* (not detected in 1 g). MoreMeat provides results from the analyses of three non-consecutive batches to demonstrate that fungal protein can be manufactured to meet the specifications. MoreMeat states that fungal protein has a shelf-life of 12 months when stored at -18°C in a vacuum-sealed aluminum bag.

MoreMeat estimates the dietary exposure to fungal protein based on the intended uses and using food consumption data from the 2021-2023 National Health and Nutrition Examination Survey (NHANES). MoreMeat estimates the mean and 90th percentile eaters-only dietary exposures to fungal protein for the U.S. population aged 2 years and older to be 94 g/person (p)/d (1.6 g/kg body weight (bw)/d) and 207 g/p/d (3.5 g/kg bw/d), respectively. MoreMeat states that fungal protein is intended to substitute for other protein sources in the diet, therefore, the intended uses of fungal protein are not expected to result in an overall increase in protein consumption in the diet.

MoreMeat discusses the safety of the intended uses of fungal protein by describing the manufacturing process controls, comprehensive analytical testing, toxicology studies, allergenicity assessment, and dietary exposure analysis, in addition to discussing the substantial similarity to other *Fusarium*-derived proteins that have been the subjects of previous GRAS notices. MoreMeat states that macronutrient levels in fungal protein are within the acceptable ranges set by the Institute of Medicine. MoreMeat reports that the level of residual nucleic acids in fungal protein is similar to or lower than levels present in common foods and that dietary exposure to RNA from consumption of fungal protein is safe. MoreMeat states that mycotoxin exposure from fungal protein consumption results in cumulative estimated daily intakes well below existing dietary exposure levels and established safety thresholds. MoreMeat discusses a recently published short-term

rat study involving fungal protein that did not cause adverse effects in the endpoints measured and unpublished studies that report fungal protein is not genotoxic. MoreMeat also references published toxicology data from GRNs 000904 and GRN 000945[1] supporting the safety of related *Fusarium* fungal proteins, including acute, subchronic, chronic, reproductive, and developmental toxicity studies showing no adverse effects. Fungal protein was evaluated using literature review and bioinformatic analyses, and MoreMeat confirms that no evidence was found showing that fungal protein could pose a significant risk of allergenicity or toxicity to consumers. MoreMeat conducted a literature search through July 2025 and did not identify any information that would contradict its GRAS conclusion. MoreMeat states that they conducted a tasting survey in addition to serving participants in conferences since 2022 and no tolerability issues or adverse effects have been reported.

Based on the totality of the data and information, MoreMeat concludes that fungal protein is GRAS for its intended use.

Standards of Identity

In the notice, MoreMeat states its intention to use fungal protein in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. 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 fungal protein 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. 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.

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

[1] Fungal protein from *Fusarium flavolapis* and *Fusarium venenatum* were the subjects of GRNs 000904 and GRN 000945, respectively. We evaluated these notices and responded in letters dated March 26, 2021, and April 22, 2022, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.

have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of MoreMeat's notice concluding that fungal protein 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 fungal protein. Accordingly, our response should not be construed to be a statement that foods containing fungal protein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that MoreMeat provided, as well as other information available to FDA, we have no questions at this time regarding MoreMeat's conclusion that fungal protein is GRAS under its intended conditions of use. This letter is not an affirmation that fungal protein 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 001255 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.11.18 12:05:19 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program