Henrike Wemekamp-Kamphuis, Ph.D.
Jovie USA LLC
1600 Golf Road Corporate Center
Suite 1200
Rolling Meadows, IL 60008

Re: GRAS Notice No. GRN 001136

Dear Dr. Wemekamp-Kamphuis:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001136. We received Jovie USA LLC (Jovie)'s notice on February 23, 2023, and filed it on May 25, 2023. Jovie submitted an amendment to the notice on August 31, 2023, that addressed issues with the intended use, composition, manufacturing, specifications, dietary exposure, safety data and information, and the literature search conducted.

The subject of the notice is dry whole goat milk (DWGM) for use as a source of protein in goat-milk based, ready-to-feed or powdered, non-exempt infant formula for term infants at a maximum level of 5.5 g/100 mL[1] of infant formula as consumed. The notice informs us of Jovie's view that this use of DWGM is GRAS through scientific procedures.

Our use of the term, "DWGM," 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 Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "DWGM."

Jovie describes DWGM as a homogeneous, off-white, free-flowing powder obtained from fresh goat milk. Jovie discusses the similarities of DWGM to dry whole cow milk as defined in 21 CFR 131.147. Jovie states that DWGM contains lactose, proteins, fat, and minerals in the same relative proportions as the milk from which it was made. Jovie

[1] Jovie states that the maximum intended use level for DWGM in powdered infant formula is 42% by weight and based on a reconstitution rate of 13 g infant formula powder/100 mL of formula as consumed, the maximum use level is equivalent to 5.5 g/100 mL.

notes that DWGM does not contain added vitamins A and D or other optional ingredients, which are permitted in dry whole cow milk per 21 CFR 131.147. Jovie discusses the composition of the lipid fraction of goat milk and notes that the total fat content and fatty acid profiles of goat milk are similar to cow milk, although Jovie notes that goat milk has higher levels of caprylic and capric acids. In addition, Jovie states that goat milk contains similar levels of cholesterol and phospholipids, including sphingolipids, compared to cow and human milk.

Jovie describes the manufacture of DWGM. Raw goat milk is pasteurized, cooled, and stored at ≤6 °C for up to 48 hours. The pasteurized milk is then concentrated by evaporation and spray dried to produce a powder. The DWGM powder is sieved and packaged. Jovie states that DWGM is manufactured using good manufacturing practices and standard dairy processing techniques, and that no component of the whole goat milk is concentrated to greater than naturally occurring levels on a dry basis. Jovie states that the goat milk starting material used to produce DWGM is produced in accordance with all applicable standards and certification requirements for fluid milk and is pasteurized and produced in accordance with the provisions of the Pasteurized Milk Ordinance (PMO, 2019).

Jovie provides specifications for DWGM that include the minimum content of protein (≥34% of milk solids, not fat), fat (26-35%), and limits for moisture (≤5%), titratable acidity (≤18 mL 0.1 N NaOH/10 g of solids, not fat), scorched particles (≤Disc B), arsenic (<0.1 mg/kg), cadmium (<0.01 mg/kg), lead (<0.15 mg/kg), mercury (<0.01 mg/kg), chromium (<2 mg/kg), and limits for microorganisms, including *Salmonella* serovars (absent in 25 g), *Bacillus cereus* (< 100 colony forming units/g), and *Cronobacter* sp. (absent in 100 g). Jovie provides the results from three non-consecutive batch analyses to demonstrate that DWGM can be manufactured to meet these specifications. Jovie states that the shelf-life of DWGM is at least 1 year when stored in a cool and dry environment (10-30 °C, <70% relative humidity).

Jovie estimates the dietary exposure to DWGM based on the intended use and published estimates of the energy requirements for infants 1 to 12 months of age. Jovie notes that total energy requirements increase with age and are higher in males than females. The highest energy requirements on a body weight (bw) basis are at 1 month of age at 113 kcal/kg bw/d for males and 107 kcal/kg bw/d for females. Based on the caloric content of a goat milk-based infant formula as consumed (0.65-0.67 kcal/mL) and the maximum intended use level of DWGM, Jovie estimates the dietary exposure to DWGM to be 9.4 g/kg bw/d for males 1 month of age and 8.9 g/kg bw/day for females 1 month of age. Jovie estimates the dietary exposure to DWGM on a body weight basis for each month of age for infants up to 12 months assuming infant formula is the sole source of nutrition; however, Jovie notes that infant diets typically begin to transition to solid foods at 4 to 6 months of age.

Jovie discusses publicly available data and information to support the safety of DWGM. Jovie states that while they found no traditional toxicology studies on DWGM, several studies were found that focused on whole goat milk with respect to nutritive value and/or bioavailability of specific minerals, none of which reported adverse effects. Jovie

also discusses data and information regarding the quality of protein and fat content and concludes that the use of DWGM is safe when used as an ingredient for infant formula per 21 CFR 107.100. Jovie states that the quality of goat milk protein is considered similar to casein controls as assessed by classic Protein Efficiency Ratio studies. Jovie also discusses studies in piglets and *in vitro* models showing that goat milk digestibility is comparable to that of cow milk. Jovie discusses five feeding studies with infants that support their conclusion that goat milk protein-based infant formula provides growth and nutritional outcomes in infants similar to those provided by a standard cow milk-based infant formula. Jovie states that although allergy to goat milk in the absence of cow milk allergy has not been described in infants younger than 1 year of age, several published studies have shown that consumers with cow milk allergy may show cross-reactivity towards goat milk proteins.[2]

Based on the totality of the data and information, Jovie concludes that DWGM is GRAS for its intended use.

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 DWGM 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. OFAS 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.

Intended Use in Infant Formulas

Under section 412 of the Federal Food, Drug, & Cosmetic (FD&C) Act, a manufacturer of a new infant formula must make a submission to FDA providing required assurances about the formula at least 90 days before the formula is marketed. Our response to Jovie's GRAS notice does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing DWGM to make the submission required by section 412. Infant formulas are the purview of 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

[2] Jovie states that DWGM-based infant formula will not be marketed as an alternative to hypoallergenic infant formula for the management of cow milk allergy.

section 301(ll)(1)-(4) applies. In our evaluation of Jovie's notice concluding that DWGM 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 DWGM. Accordingly, our response should not be construed to be a statement that foods containing DWGM, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Jovie provided, as well as other information available to FDA, we have no questions at this time regarding Jovie's conclusion that DWGM is GRAS under its intended conditions of use. This letter is not an affirmation that DWGM 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 001136 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.10.31 13:37:59 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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