



Katrina Emmel, Ph.D.  
KemmelCal Inc.  
947 Martina Circle  
Corona, CA 92879

Re: GRAS Notice No. GRN 001189

Dear Dr. Emmel:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001189. We received Bubs Australia Limited (Bubs)'s notice on May 2, 2024, and filed it on May 15, 2024. Bubs submitted an amendment to the notice on August 6, 2024, that clarified the specifications and aspects of the safety narrative.

The subject of the notice is dry whole goat milk (DWGM) for use as an ingredient in goat milk-based, non-exempt infant formula for term infants at a level up to 20% (w/w) of powdered formula. The notice informs us of Bubs' 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 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 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."

Bubs describes DWGM as a homogeneous, creamy-white, free flowing powder that is obtained from fresh goat milk. Bubs discusses the similarities of DWGM to dry whole cow milk as defined in 21 CFR 131.147. Bubs states that DWGM contains proteins, fat, lactose, and minerals in the same relative proportions as the milk from which it was made. Bubs notes that DWGM does not contain added vitamins A and D or other optional ingredients permitted in dry whole milk by U.S. regulation. Bubs discusses published information on the composition of whole goat milk and analytical results for DWGM to describe the typical proximate, amino acid, fatty acid, mineral, and vitamin content. In addition, Bubs also discusses published information to demonstrate that whole goat milk contains similar levels of cholesterol and phospholipids as cow and human milk.

Bubs describes the manufacture of DWGM using current good manufacturing practices

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(cGMP) and standard dairy processing techniques. Bubs states that the goat milk starting material also is produced in accordance with cGMP and meets all applicable standards and certification requirements for fluid milk. Raw goat milk is pasteurized, filtered, and stored for up to four days. The pasteurized milk is spray dried to produce the DWGM powder, which is then sieved and packaged. Bubs notes that no component of the whole goat milk is concentrated to greater than naturally occurring levels on a dry basis.

Bubs provides specifications for DWGM that include the minimum content of protein  $\geq$  34% of milk solids, not fat and  $>$  25% on an as-is basis), fat (26-40%), and limits for free fat ( $<$  5%), moisture ( $<$  4%), ash ( $<$  8 %), titratable acidity (7-14 °T), scorched particles  $\leq$  Disc A), peroxide value ( $<$  3 milliequivalents O<sub>2</sub>/kg fat), arsenic ( $<$  0.1 mg/kg), cadmium ( $<$  0.01 mg/kg), lead ( $<$  0.02 mg/kg), mercury ( $<$  0.01 mg/kg), tin ( $<$  50 mg/kg), and microorganisms, including *Salmonella* serovars (absent in 375 g), *Bacillus cereus* ( $<$  50 colony forming units/g), *Listeria* spp. (absent in 25 g), and *Cronobacter* spp. (absent in 300 g). Bubs provides the results of seven non-consecutive batch analyses to demonstrate that DWGM can be manufactured to meet these specifications. Based on the results of an ongoing stability study, Bubs states that DWGM is stable for at least 19 months when stored under ambient conditions.

Bubs estimates the dietary exposure to DWGM based on the intended use and published estimates of the energy requirements for infants up to 12 months of age. Bubs 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, 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 (68.6 kcal/100 mL) and the maximum intended use level of DWGM, Bubs estimates the highest dietary exposures to DWGM to be 4.5 g/kg bw/d for males and 4.3 g/kg bw/d for females. Bubs also estimates the dietary exposure to DWGM for infants up to 12 months assuming that infant formula is the sole source of nutrition; however, Bubs notes that infant diets typically begin to transition to solid foods at 4 to 6 months of age.

Bubs discusses publicly available data and information to support the safety of DWGM. Bubs states that the European Food Safety Authority's 2012 opinion on the suitability of goat milk protein supports the regulatory and scientific consensus on the safety and suitability of using goat milk as a dietary protein in infant formula. Bubs discusses published studies regarding the digestion of goat milk and goat milk infant formula using simulated *in vitro* models and animal studies, and states that these studies do not raise any safety concerns regarding the intended use of DWGM. In further support of the safety of DWGM, Bubs cites a number of other animal and infant feeding studies on goat milk and/or ingredients derived from goat milk, none of which reported adverse effects. Bubs also discusses published human studies using goat milk or components of goat milk and concludes that none of the clinical studies reviewed raised safety concerns or indicated a difference in growth or safety measures between infants fed formulations containing cow milk or goat milk.

Bubs compares the amino acids present in DWGM to dry whole goat milk from GRN

001136<sup>1</sup> and the Codex standard for human milk. Bubs discusses the fatty acid distribution of goat, cow, and human milk, and states that goat and cow milk have a comparable total fat content and similar fatty acid profile. Bubs states that DWGM is neither the sole source of protein nor fat, and that the final infant formula will be supplemented with other protein and fat sources as needed under 21 CFR 107.100.

Bubs asserts that while individuals with cow milk protein allergy (CMPA) may experience cross-reactivity to goat milk proteins, there is no indication that goat milk is more allergenic than cow milk. Furthermore, Bubs states that DWGM is not intended for use in infant formula marketed as an alternative to hypoallergenic formulas for infants with CMPA.

Based on the totality of the data and information, Bubs 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 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 Bubs' 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 section 301(ll)(1)-(4) applies. In our evaluation of Bubs' notice concluding that DWGM

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<sup>1</sup> Dry whole goat milk was the subject of GRN 001136. We evaluated this notice and responded in a letter dated October 31, 2023, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

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 Bubs provided, as well as other information available to FDA, we have no questions at this time regarding Bubs' 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 001189 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

Susan J.  
Carlson -S

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