U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Amy Mozingo
GRAS Associates, LLC
11810 Grand Park Ave, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001212

Dear Ms. Mozingo:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001212. We received the notice that you submitted on behalf of Crossway Foods Limited (Crossway) on September 19, 2024, and filed it on October 21, 2024. Crossway submitted an amendment on January 13, 2025, that clarified the intended use, specifications, dietary exposure, and aspects of the safety narrative.

The subject of the notice is liquid whole goat milk for use as a source of protein and other nutrients in goat milk-based, non-exempt infant formula for term infants at a use level up to 40% by dry weight of the finished product.[1,2] The notice informs us of Crossway's view that this use of liquid whole goat milk is GRAS through scientific procedures.

Our use of the term, "liquid whole goat milk," 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 "liquid whole goat milk."

Crossway describes the identity and composition of liquid whole goat milk, including the similarities to whole cow milk as defined in 21 CFR 131.110. Crossway notes that liquid whole goat milk contains higher concentrations of vitamin A and potassium and lower concentrations of folic acid and vitamin B_{12} compared to cow milk. In addition,

[1] Crossway states that liquid whole goat milk is not intended for use in hypoallergenic infant formula or for infants with cow milk protein allergy.
[2] Crossway states the maximum intended use level is equivalent to 320 g of liquid whole goat milk per 100 g of dry infant formula.

Crossway states that whole goat milk contains a similar fatty acid profile to cow milk, although goat milk contains slightly higher levels of medium chain triglycerides, monounsaturated fatty acids, and polyunsaturated fatty acids. Crossway provides a summary of published data and batch analyses to describe the composition of liquid whole goat milk, including the lipid, fatty acid, and amino acid profiles and content of various vitamins and minerals. Crossway describes the average proximate composition of liquid whole goat milk to include moisture, lactose, fat, protein, and ash.

Crossway describes the method of manufacture for liquid whole goat milk, stating that the starting material, raw whole goat milk, is filtered and pasteurized in accordance with the conditions specified in the Pasteurized Milk Ordinance. Following pasteurization, the milk is then cooled and stored at <7.2 °C for up to 72 hours prior to its use in the production of infant formula. Crossway states that liquid whole goat milk is produced according to current good manufacturing practices and that all raw materials, processing aids, and food contact substances used are food-grade and permitted by U.S. regulations or have previously been determined to be GRAS for their respective uses.

Crossway provides specifications for liquid whole goat milk that include protein content (2.0-3.5%), fat (2.5-4.5%), moisture (87.5-89.5%), and limits for lactose (≤4.6%), titratable acidity (<0.18% lactic acid), and pH (6.0-7.5). Crossway provides additional specifications that are used for the periodic monitoring of raw whole goat milk and testing milk from new suppliers. These specifications include limits for nitrates (≤20 mg/kg), nitrites (≤1 mg/kg), arsenic (≤0.02 mg/kg), cadmium (≤0.01 mg/kg), lead (≤0.02 mg/kg), mercury (≤0.02 mg/kg), and microorganisms, including *Cronobacter* spp. (absent in 10 g), *Salmonella* serovars (absent in 25 g), and *Listeria monocytogenes* (absent in 25 g). Crossway provides the results from four non-consecutive batch analyses to demonstrate that liquid whole goat milk can be manufactured to meet these specifications. Crossway notes that in the production of infant formula, liquid whole goat milk is combined with other ingredients to form an intermediate product that is subjected to a heat-treatment step, evaporation, and spray drying. Crossway provides specifications for the intermediate product that includes limits for *Cronobacter* spp. (absent in 300 g) and *Salmonella* serovars (absent in 250 g). Further, Crossway provides specifications for the final infant formula product that includes limits for *Cronobacter* spp. (absent in 300 g), *Salmonella* serovars (absent in 1500 g), and *Listeria monocytogenes* (absent in 250 g).

Crossway estimates the dietary exposure to liquid whole goat milk based on the intended use and infant formula consumption data from the 2017-2020 National Health and Nutrition Examination Survey. Crossway reports the mean and 90th percentile estimates of infant formula consumption for male and female infants 0-6 and 7-12 months of age and estimates dietary exposure to liquid whole goat milk based on the maximum intended use level on a dry matter basis of 40 g/100 g formula powder and a recommended reconstitution rate of approximately 12.9 g/100 mL of formula as consumed. Crossway estimates the mean and 90th percentile eaters-only dietary exposure to liquid whole goat milk for 0-6 months of age to be 331.0 g/person (p)/d (52.7 g/kg body weight (bw)/d) and 503.7 g/p/d (80.2 g/kg bw/d), respectively, and estimates the mean and 90th percentile dietary exposure to the ingredient on a dry

matter basis to be 41.4 g/p/d (6.6 g/kg bw/d) and 63.0 g/p/d (10.0 g/kg bw/d), respectively. Crossway estimates the mean and 90th percentile eaters-only dietary exposure to liquid whole goat milk for 7-12 months of age to be 274.3 g/p/d (29.6 g/kg bw/d) and 461.1 g/p/d (49.7 g/kg bw/d), respectively, and estimates the mean and 90th percentile dietary exposure to the ingredient on a dry matter basis to be 34.3 g/p/d (3.7 g/kg bw/d) and 57.6 g/p/d (6.2 g/kg bw/d), respectively.

Crossway discusses the publicly available safety data and information for liquid whole goat milk found in the literature and in GRNs 000644[3] and GRN 001136.[4] This includes information on the history of consuming goat milk, as well as a discussion on allergenicity and human clinical studies as evidence to support the safety of using liquid whole goat milk.

To support safety, Crossway cites a long history of safe consumption of goat milk, dating back at least 6000 years. Crossway also identifies and discusses a pivotal published study that was conducted in healthy, term infants up to 6 months of age. This study by Zhou et al. (2014) was a randomized, double-blind controlled trial where infants receiving a goat milk-based formula were compared to infants that were fed a cow milk-based formula or human milk, at levels up to 1 L/day. Crossway states that there were no significant differences in growth parameters or adverse events reported between the formula and breastfed groups. Crossway also summarizes published clinical studies that utilized infant formulas that were made with skimmed goat milk or contained a combination of goat and cow milk. Crossway notes that these corroborative studies support the safety and tolerability of goat milk-based infant formula. Crossway also states that the final goat milk-based infant formula into which liquid whole goat milk will be incorporated will comply with 21 CFR 107.100. Additionally, Crossway reviews published animal and human studies related to goat milk allergenicity and concludes that goat milk does not pose an increased risk of allergenicity when compared to cow milk.[1]

Based on the totality of the data and information, Crossway concludes that liquid whole goat milk is GRAS for its intended use.

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 Crossway's GRAS notice does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing liquid whole goat milk to make the submission required by section 412. Infant formulas are the purview of

[3] A combination of nonfat dry goat's milk and goat whey protein concentrate was the subject of GRN 000644. We evaluated this notice and responded in a letter dated October 11, 2016, stating that we had no questions at that time regarding the notifier's GRAS conclusion.
[4] 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.

the Office of Critical Foods in NCE.

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 Crossway's notice concluding that liquid whole goat milk 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 liquid whole goat milk. Accordingly, our response should not be construed to be a statement that foods containing liquid whole goat milk, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Crossway provided, as well as other information available to FDA, we have no questions at this time regarding Crossway's conclusion that liquid whole goat milk is GRAS under its intended conditions of use. This letter is not an affirmation that liquid whole goat milk 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 001212 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.02.07 14:17:10 -05'00'

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