



Mary Murphy, M.S., R.D.
Exponent
1150 Connecticut Avenue, NW
Suite 1100
Washington, D.C. 20036

Re: GRAS Notice No. GRN 001041

Dear Ms. Murphy:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001041. We received the notice that you submitted on behalf of Nara Organics, Inc. (Nara Organics) on November 12, 2021, and filed it on February 15, 2022. Nara Organics submitted an amendment to the notice on April 13, 2022, that clarified the intended use and specifications, as well as confidential supplier information provided in the notice.

The subject of the notice is dry whole milk for use as an ingredient in cow milk-based, non-exempt infant formula for term infants at a maximum level of 22% (w/w) powdered infant formula. The notice informs us of Nara Organics' view that this use of dry whole milk is GRAS through scientific procedures.

Nara Organics describes the identity of dry whole milk as defined in 21 CFR 131.147. Nara Organics states that dry whole milk is composed of carbohydrates (primarily in the form of lactose), proteins, fats, and minerals in the same relative proportions as the cow milk from which it was produced. Nara Organics reports the typical proximate composition of dry whole milk to include carbohydrates (36%), proteins (26%), fats (30%), ash (5%) and moisture (3%). Nara Organics notes that its dry whole milk does not contain added vitamins A and D or other optional ingredients permitted in dry whole milk (21 CFR 131.147). Nara Organics discusses the protein and fat constituents of dry whole milk. Protein in dry whole milk contains the same casein:whey ratio (approximately 80:20) as in nonfat dry milk commonly used in non-exempt infant formulas. The fat in dry whole milk contains predominantly triglycerides, with minor amounts of phospholipids (average of 0.23% of dry whole milk) and cholesterol. Major fatty acids in dry whole milk include myristic, palmitic, stearic, and oleic acids.

Nara Organics describes the manufacture of dry whole milk. Raw cow milk is filtered and pasteurized prior to an evaporation step that partially removes water. After evaporation, the pasteurized milk is spray dried to form a powder. Nara Organics states that the cow milk starting material in the manufacture is Grade "A," produced in

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accordance with all applicable standards and certification requirements for fluid milk, and pasteurized in accordance with the provisions of the Pasteurized Milk Ordinance (PMO, 2019). Nara Organics states that it uses standard dairy processing techniques and that no component of the whole milk is concentrated to greater than naturally occurring levels on a dry basis.

Nara Organics provides specifications for dry whole milk that include protein (22-30%), fat (26-35%), moisture ($\leq 4.5\%$), titratable acidity ($\leq 0.15\%$), peroxide value (≤ 5 meq/kg fat), scorched particles (≤ 15 mg), cholesterol (≤ 150 mg/100 g), and ash ($\leq 7\%$), as well as limits for vitamins A and D and several minerals naturally present in whole milk. Nara Organics also provides limits for heavy metals, including arsenic (≤ 0.1 mg/kg), cadmium (≤ 0.05 mg/kg), lead (≤ 0.05 mg/kg), and mercury (≤ 0.05 mg/kg), and limits for microorganisms, including *Salmonella* serovars (absent in 375 g¹), *Bacillus cereus* (< 100 CFU/g), and *Cronobacter* sp. (absent in 10 g). Nara Organics provides the results of three non-consecutive batch analyses to demonstrate that the dry whole milk can be manufactured to meet these specifications. Nara Organics states that the shelf-life of dry whole milk is consistent with other commercially available dry whole milk powders and is up to 2 years when stored in a cool, dry, odor-free environment.

Nara Organics estimates the dietary exposures to dry whole milk from the intended use and infant formula consumption data from the What We Eat in America component of the National Health and Nutrition Examination Survey (2011-2018). At the maximum intended use level of 22 g/100 g formula powder Nara Organics calculates the use level of dry whole milk to be equivalent to 4.3 g/100 kcal of formula as consumed, based on a reconstitution rate of 13 g formula powder/100 mL and a caloric content of 67.6 kcal/100 mL for formula as consumed. Nara Organics provides estimates of dietary exposure to dry whole milk for infants up to one year of age (i.e., 0-2 months, 3-5 months, 6-8 months, and 9-11 months). The reported mean and 90th percentile dietary exposures (users only) are in the range of 19 to 23 g/d and 30 to 36 g/d, respectively, across the first year of life. Nara Organics determined that infants 3-5 months of age have the highest dietary exposures with mean and 90th percentile estimates of 23 and 36 g/d, respectively. Infants 0-2 months of age have the highest dietary exposures on a body weight (bw) basis with mean and 90th percentile estimates of 4.1 and 6.3 g/kg bw/d, respectively. Further, Nara Organics states that the intended use of dry whole milk is expected to contribute a fraction of the total protein (49%), total fat (21%), and total carbohydrates (16%) in infant formula for term infants.

Nara Organics discusses published data and information to support the safety of dry whole milk. Nara Organics states that whole milk and dry whole milk are widely consumed by infants, children, and adults with no adverse effects other than allergic reactions in susceptible individuals. Nara Organics discusses key physico-chemical similarities and differences between unmodified, dry whole milk and nonfat dry milk arising from processing and concludes that the use of dry whole milk is not different from the current use of nonfat dry milk and whey powder ingredients in infant formula. Nara Organics states that dry whole milk will provide a source of constituents typically

¹ The method used for the *Salmonella* test is validated for this sample size.

present in lower concentrations in infant formula, namely phospholipids and other lipids present in milk fat but not present in vegetable oils. Nara Organics concludes that the levels of these components provided by the intended use of dry whole milk will result in levels similar to or well below the mean concentrations reported in human milk. Nara Organics discusses published clinical studies in infants and young children fed whole milk or constituents derived from whole milk to support the safety of its ingredient as a part of the infant diet. Nara Organics states that the intended use of dry whole milk as an ingredient in infant formula provides only a portion of protein, fat, or other nutrients in the total formula, precluding any safety concerns associated with feeding infants whole milk. Nara Organics states that infant formula containing dry whole milk is expected to meet all nutrient specifications for infant formula listed in 21 CFR 107.100.

Based on the totality of the data and information, Nara Organics concludes that dry whole milk 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 dry whole milk 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 the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety 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.

Allergen Labeling

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a “major food allergen” declare the allergen’s presence (section 403(w)). The FD&C Act defines a “major food allergen” as one of nine foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame (effective January 1, 2023)) or a food ingredient that contains protein derived from one of those foods. Dry whole milk requires labeling under the FD&C Act because it is a “major food allergen.”

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 Nara Organics’ GRAS notice does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing dry whole milk 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 Nara Organics' notice concluding that dry whole 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 dry whole milk. Accordingly, our response should not be construed to be a statement that foods containing dry whole milk, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Nara Organics provided, as well as other information available to FDA, we have no questions at this time regarding Nara Organics' conclusion that dry whole milk is GRAS under its intended conditions of use. This letter is not an affirmation that dry whole 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 001041 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Date: 2022.05.10 15:26:11 -04'00'

Susan Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition