



Kinya Tsuchiya
The Nisshin OilliO Group, Ltd.
1-23-1 Shinkawa, Chou-ku
Tokyo 104-8285
JAPAN

Re: GRAS Notice No. GRN 001050

Dear Mr. Tsuchiya:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001050, which we filed on April 6, 2022. We received this request on July 12, 2022.

The subject of the notice is high 2-palmitic acid vegetable oil for use as a source of fat in non-exempt and exempt infant formula for term and pre-term infants, respectively, at a level up to 70% of total fat. High 2-palmitic acid vegetable oil is also intended to replace other sources of fat in a variety of foods, including use in infant and toddler foods, and in baked goods and baking mixes, breakfast cereals, cheese-based spreads, snack dips, dairy product analogs, meal-replacements, margarine-type spreads, mayonnaise-type dressing, salad dressings, frozen dairy desserts and mixes, gelatins, puddings and fillings, grain products and pastas, white sauces and milk gravies, hard candy, milk drinks, meat analogs, grain-based soups, soft candy, and grain-based salty snacks at a level of 100% of total fat. The notice informs us of The Nisshin OilliO, Ltd. (Nisshin OilliO)'s (you, your) view that these uses of high 2-palmitic acid vegetable oil are GRAS through scientific procedures.


In emails dated June 27, 2022, and July 1, 2022, we informed you that we had concerns regarding the following: 1. missing information on the intended use and manufacturing, 2. the presence of 3-monochloropropane-1,2-diol esters and glycidyl esters in high-2 palmitic acid vegetable oil and its use in infant formula, and 3. an insufficient safety narrative in Part 6 of the notice, particularly regarding the use of high-3 palmitic acid vegetable oil in pre-term infant populations. In an email dated July 1, 2022, we recommended that you request that we cease our evaluation of GRN 001050, which you did on July 12, 2022.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001050 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

 Digitally signed by Susan J.
Carlson -S
Date: 2022.07.18 11:12:55
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Melvin Carter, Ph.D.
Director
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