



Allison Gebbie
Apeel Sciences
71 South Los Carneros Road
Goleta, CA 93117

Re: GRAS Notice No. GRN 000648

Dear Ms. Gebbie:

The Food and Drug Administration (FDA, we) completed our evaluation of Apeel Sciences (Apeel)'s supplement to GRN 000648. We received the supplement on April 12, 2024. The supplement provides an update regarding the use of the subject of GRN 000648.

We previously responded to GRN 000648 on December 13, 2016. We stated that we had no questions at that time regarding Apeel's conclusion that 1- and 2-monoglycerides primarily of palmitic acid (monoglycerides) is GRAS for the intended uses as a surface-finishing agent and/or texturizer to protect freshness and extend shelf-life of agricultural products such as fruits (e.g., berries, grapes, citrus, bananas, mangoes, avocados) and vegetables (e.g., legumes, roots, tubers). The monoglycerides form a thin, edible physical barrier against moisture loss and oxidation when applied to the surfaces of certain fruits and vegetables.

In the supplement dated April 12, 2024, Apeel informs the FDA that at the time of submitting GRN 000648, the process described in the notice to make monoglycerides was in a proof-of-concept stage of development, had not been commercialized, and that Apeel has no plans to commercialize the monoglycerides that were the subject of GRN 000648. Further, Apeel indicates that the monoglycerides that Apeel is using are manufactured via the process described in 21 CFR 184.1505.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 issuing this additional correspondence, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing monoglycerides. Accordingly, our additional correspondence should not be construed to be a statement that foods containing monoglycerides, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

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)(2), the text of this letter responding to the supplement to GRN 000648 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson

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Carlson -S
Date: 2024.05.24 15:00:51
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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition