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

Re: GRAS Notice No. GRN 000886

Dear Ms. Gebbie:

The Food and Drug Administration (FDA, we) completed our evaluation of Apeel Sciences (Apeel)'s supplement to GRN 000886. We received the supplement on April 12, 2024. The supplement provides an update regarding the use of the subject of GRN 000886. Apeel submitted clarifying information on the terminology used in the supplement on May 6, 2024.

We previously responded to GRN 000886 on July 13, 2020.[1] We stated that we had no questions at that time regarding Apeel's conclusion that a mixture of mono- and diacylglycerides derived from grape seed (MDAG) is GRAS for the intended uses as a component of a surface finishing agent to protect the freshness and extend the shelf life of fresh produce. MDAG forms 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 000886, the process described in the notice to make MDAG was in a proof-of-concept stage of development, had not been commercialized, and that Apeel has no plans to commercialize the MDAG that were the subject of GRN 000886. Further, Apeel indicates that the MDAG 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 MDAG. Accordingly, our additional correspondence should not be construed to be a statement that foods containing MDAG, if introduced or delivered for introduction into interstate commerce, would not violate

[1] We issued a corrected response letter on September 11, 2020.

section 301(ll).

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000886 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2024.05.24 15:02:22 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition