U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Dr. Corinna Dwan
Marinova Pty. Ltd.
249 Kennedy Drive
Cambridge, Tasmania 7170
AUSTRALIA

Re: GRAS Notice No. GRN 000565

Dear Dr. Dwan:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Marinova Pty. Ltd. (Marinova) to GRN 000565. We received the supplement on December 30, 2024. The supplement addresses an expanded intended use in sports drinks for the subject of GRN 000565. Marinova submitted clarifying information on May 8, 2025, regarding the use level, methods of analysis, dietary exposure, aspects related to safety, and specifications.

We previously responded to GRN 000565 on July 2, 2015. We stated that we had no questions at that time regarding Marinova's conclusion that fucoidan derived from *Undaria pinnatifida* (fucoidan) is GRAS for the intended use as an ingredient in baked goods, soups, snack foods, imitation dairy products, and seasonings/flavors at up to 30 mg/serving, excluding use in infant formula and products under the U.S. Department of Agriculture (USDA) jurisdiction.

In the supplement dated December 30, 2024, Marinova informs us of its view that fucoidan is GRAS, through scientific procedures, for use as an ingredient in sports drinks up to 30 mg per serving.

Our use of the term, "fucoidan," 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 non-standardized 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 "fucoidan."

In the supplement, Marinova provides information on the identity of the fucoidan and states that it is produced the same way as described in GRN 000565. Marinova revises the specification limit for arsenic, from ≤1 mg/kg to <0.5 mg/kg, and mercury from ≤2 mg/kg to <0.5 mg/kg. Marinova also provides the results from the analyses of nine non-

consecutive batches to demonstrate that fucoidan can be manufactured to meet these specifications.

In the supplement Marinova provides an updated estimate of the dietary exposure to fucoidan that includes the previously notified uses[1], the expanded use in sports drinks, as well as other dietary sources. Based on food consumption data from the 2017-March 2020 National Health and Nutrition Examination Survey, Marinova estimates the cumulative mean and 90th percentile eaters-only dietary exposure to fucoidan for the U.S. population aged 2 years and older to be 99 mg/person (p)/d (1.5 mg/kg body weight (bw)/d) and 131 mg/p/d (2.5 mg/kg bw/d), respectively.

Marinova states that an updated literature search was conducted through August 2024 and discusses the increase in dietary exposure to fucoidan due to the expanded intended uses and how this increase would not raise safety concerns. Marinova states that new literature is consistent with literature discussed in the original submission that suggests fucoidan extracts from various sources are poorly absorbed through oral exposure, indicating low oral bioavailability and are thus primarily eliminated in feces. Marinova summarizes and discusses thirteen studies identified in the updated literature search. Marinova states that overall, new studies continue to reveal that fucoidan derived from *Undaria pinnatifida* and other related species is non-toxigenic, non-mutagenic, and no serious adverse effects are reported in any of the studies, including a 180-day repeat oral toxicity study in rats that Marinova considers pivotal. Marinova also summarizes and discusses twenty-six studies identified in the updated literature search. Marinova states that any reports of physiologically effects that relate to safety, including potential anticoagulation effects, identified in the new literature search are not a safety concern because these observations were made using modified and/or depolymerized fucoidan species, unlike the fucoidan that is the subject of GRN 000565, whose manufacturing processes do not involve chemical modification or hydrolysis steps intended to reduce molecular weight or enhance gastrointestinal absorption.

Based on the totality of the data and information, Marinova concludes that fucoidan is GRAS under the conditions of its intended use.

Standards of Identity

In the supplement, Marinova states its intention to use fucoidan in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

[1] Fucoidan concentrate from *Fucus vesiculosus* was the subject of GRN 000661. We evaluated this notice and responded in a letter dated February 10, 2017, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (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 fucoidan 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 ONFL in the NCE. OPMAS 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.

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 Marinova's supplement concluding that fucoidan 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 fucoidan. Accordingly, our response should not be construed to be a statement that foods containing fucoidan, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Marinova provided, as well as other information available to FDA, we have no questions at this time regarding Marinova's conclusion that fucoidan is GRAS under its intended conditions of use. This letter is not an affirmation that fucoidan 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 the supplement to GRN 000565 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.09.15 16:45:49 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program