

Memorandum

Date: October 14, 2022

From: Biologist, Division of Science and Technology (HFS-255)

Subject: FAP 9A4823 – Amending Part of 21 CFR to provide safe use of vitamin D₃ in breakfast cereals as defined in 21 CFR 170.3(n)(4) and in grain-based nutrition bars.

Petitioner: Kellogg Company.

Agent: Hogan Lovells US LLP.

To: Lane Highbarger, Consumer Safety Officer, Division of Food Ingredients, HFS-255

Through: Mariellen Pfeil, Lead Biologist, Office of Food Additive Safety (HFS-255)

We have reviewed the claim of categorical exclusion for the above referenced petition and have concluded that the categorical exclusion is warranted. The claim of categorical exclusion cites the section, 21 CFR 25.32(k), under which categorical exclusion is warranted, states compliance with the categorical exclusion criteria, and states that no extraordinary circumstances exist that require the submission of an environmental assessment (EA). A categorical exclusion under 21 CFR 25.32(k) pertains to, among other things, actions to approve a food additive petition for “substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.”

This petition requests amendment to the food additive regulations in part 172 Food Additives Permitted for Direct Addition to Food for Human Consumption (21 CFR part 172) to allow for the use of vitamin D₃ in breakfast cereals as defined in 21 CFR § 170.3(n)(4) and in grain-based nutrition bars (e.g., granola bars).

Micronutrients, as opposed to macronutrients (protein, carbohydrates, and fat), are comprised of vitamins and minerals which are required in small quantities to ensure normal metabolism, growth, and physical well-being. Vitamin D₃ is a micronutrient, which when used as a food additive, remains in the food through ingestion and does not replace macronutrients in the food. Furthermore, our independent review of the petition did not identify any extraordinary circumstances and we have not received any new information or comments that would affect our previous determination. Therefore, we find the claim of categorical exclusion under 21 CFR 25.32(k) is warranted and the approval of this food additive petition falls within the class of actions covered by the stated categorical exclusion.

When the petition is ready to be regulated, please use the paragraph below, in the final rule.

We previously considered the environmental effects of this rule, as stated in the August 12, 2019, *Federal Register* notice of petition for FAP 9A4823 (84 FR 39785). We stated that we had determined, under 21 CFR 25.32(k), that this action is of a type that does not individually or cumulatively have a significant effect on the

human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

If there is a change in the identity or proposed use of the food additive, please let us know.

Denis Wafula

cc: HFS-255 Wafula
File: FAP 9A4823