U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

November 16, 2026

Via Email
Ketan Vakil
Gourmend Foods, LLC
ketan@gourmendfoods.com

Dear Mr. Vakil:

I write to notify you of the United States Food and Drug Administration's ("FDA") position regarding whether Gourmend Foods, LLC's statements in food labeling about the levels of FODMAPs in a food ("FODMAP level statements") should be regulated as nutrient content claims.

Based on the Federal Food, Drug, and Cosmetic Act and FDA regulations, and consistent with FDA's approach to similar claims in the past, FDA generally does not consider FODMAP level statements to be within the scope or intended purpose of the nutrient content claim regulations. *See* 21 C.F.R. § 101.13; *see also id.* § 101.65.

More specifically, FDA views FODMAP level statements as being similar to modified lactose content claims and to "gluten-free" claims, which FDA views as avoidance claims or statements of special dietary usefulness. *See* 58 Fed. Reg. 2302, 2368-2360 (Jan. 6, 1993) (rejecting comment asking the agency to define nutrient content claims such as "free, low," and "reduced" for lactose, reasoning that such claims are not nutrient content claims because they do not relate to the nutritional value of lactose in following dietary guidelines and maintaining healthy diet practices, and agreeing with comments stating that implied lactose level claims such as "100 percent milk free" are not nutrient content claims and should instead be regulated as avoidance claims)[1]; 21 C.F.R. § 101.91 (establishing requirements for "gluten-free" claims, which are "neither nutrient content claims nor health claims" (capitalization removed)).

FDA reviews food labels on a case-by-case basis and considers claims within the context of the labeling as a whole. All label statements on food, including those that are not nutrient content claims, avoidance claims, or statements of special dietary usefulness, must be truthful and not misleading and comply with all other applicable requirements. *See, e.g.*, 21 U.S.C. § 343(a)(1).

[1] In 2017, FDA issued a warning letter to another manufacturer suggesting that the claim "low lactose content" on a whey protein product amounted to a "nutrient content claim." *See* FDA, Warning Letter, Maine Natural Health, Inc., MARCS-CMS 525870 (Dec. 19, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/maine-natural-health-inc-525870-12192017. That portion of the letter was an error, as it is inconsistent with the explanation in the 1993 preamble cited above.

FDA has evaluated the FODMAP level statements currently made on the labeling of Gourmend Foods, LLC's FDA-regulated food products and does not consider them to be nutrient content claims and does not intend to take enforcement action on them as nutrient content claims. Furthermore, FDA also does not intend to take enforcement action on them as avoidance claims or statements of special dietary usefulness.

Sincerely,

CLAUDINE J. KAVANAUGH -S

Digitally signed by CLAUDINE J. KAVANAUGH -S
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Claudine Kavanaugh
Director, Office of Nutrition and Food Labeling
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