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Date: February 14, 2024

To: Retail Food Establishments

From: Food and Lodging, ND Department of Health and Human Services

Subject: Use of Food Additives and Dietary Supplements in Retail Food Establishments

Retail food establishments may want to use additives and nonconventional substances in food or beverages. The North Dakota Food Code § 3-202.12 Additives states:

> Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186 substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 180 Tolerances for pesticides, chemicals in food, and exceptions.

It is the responsibility of the license holder to verify that all substances used in food and beverages are safe and comply with the law before it is made available to consumers. The purpose of this notice is to:

- Direct you to the statutory and regulatory requirements of food.
- Advise you to carefully consider whether the intended use of the food substance is safe and fully complies with the law before being offered to consumers.
- Remind you that it is the license holder's responsibility to provide and have readily available scientific evidence as is required to obtain approval for the use of a substance in conventional food.
- Direct you to a series of resources needed to address scientific issues associated with demonstrating the safety of a food substance.
- Advise you when a substance is not generally recognized as safe (GRAS) under the conditions of its intended use (or is not otherwise authorized by the FDA for use as a food additive in Section 201(S) of the FD&C Act), that use of the substance in conventional food is deemed unsafe and is therefore adulterated according to the North Dakota FD&C Act Title 19-02.1. The Department can take enforcement action against you to seize the product and further disciplinary action including revocation of licensure (N.D.C.C.§ 19-02.1-04 and 19-02.1-05, N.D.C.C. § 23-09-18, and N.D.A.C. § 33-33-4.1).

The federal Food, Drug, and Cosmetic Act (FD&C Act 21 U.S.C. 321) requires that any substance that is added to food intended for human consumption in the United States is:

- A food or drink defined in section 201(f) of the FD&C Act which includes combining one or more ingredients to make a food or drink.
- An approved food additive according to the FD&C Act § Section 201(s) and 21 CFR 170-180.
- An approved color additive according to the FD&C Act § Section 201(t) and 21 CFR 170.3(f).
- A substance that is generally recognized as safe (GRAS) as determined by qualified experts for the intended conditions of use according to the FD&C Act § 201(s) and 21 CFR Parts 182 and 184.
- A substance that was prior sanctioned by the U.S. Food and Drug Administration (FDA) or the US Department of Agriculture (USDA) before 1958, because of its common use as food at that time (21 CFR 181-186).
- A dietary ingredient of a dietary supplement that is generally recognized as safe (GRAS) (FD&C Act § 201(ff)(1)).

Retail food establishments can use an additive in food or drink if it is:

1. Authorized by the FDA for the intended conditions of use in food. Below are ways to look up approved additives:
    a. Find approved additives on FDA's Food Ingredient and Packaging Inventories Database (fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-inventories).
    b. Find food additives and color additives that are listed in FDA regulations (ecfr.gov/current/title-21) (21 CFR Parts 172, 173 and Parts 73, 74, 82 respectively).
2. Determined to be Generally Recognized as Safe (GRAS) under the conditions of its intended use. Navigate through the FDA's inventory of GRAS notices (cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices) and the Select Committee on GRAS Substances (SCOGS) Database (cfsanappsexternal.fda.gov/scripts/fdcc/?set=SCOGS).

    NOTE: The GRAS Notice Inventory may not be a complete list because it is updated monthly, it transitions over federal rules changes, and some substances may have received opinion letters from the FDA based on an independent GRAS determination. Anyone making an independent GRAS determination must have both:

    a. Sufficient publicly available scientific evidence to demonstrate their intended use of the ingredient in food is safe.
    b. Proof of a consensus among qualified experts that the information in (1) demonstrates the establishment's use of the ingredient is safe.

3. The additive was preapproved by the FDA or USDA before 1958, or prior sanctioned, because of its common use as food at that time (21 CFR 181).

For questions about substances added to food, contact the FDA at premarkt@fda.hhs.gov.

Claims of health benefits must be truthful. Issues concerning health claims can be answered by the FDA Office of Nutrition and Food Labeling's Questions and Answers on Health Claims in Food Labeling (https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/questions-and-answers-health-claims-food-labeling).

If you have additional questions, contact Food and Lodging or your local public health unit.

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