Food Additives and Dietary Supplements

Limitations of Use in Retail Food Establishments

Terms and Definitions

- **Food additive**: any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any food.
- **Generally recognized as safe (GRAS)**: a substance that is generally recognized, by qualified experts, as having been adequately shown to be safe under the conditions of its intended use.
- **Dietary supplement**: a product intended for ingestion that, among other requirements, contains a "dietary ingredient" intended to supplement the diet.

What is a Food Additive?

Since 1958, the federal Food Drug & Cosmetic Act (FD&C) Section 201(s) requires that all food additives are subject to premarket approval by the U.S. Food and Drug Administration (FDA). The FDA has the authority to administer regulations for the use of any food additive. Premarket approval is not required if the proposed use of the substance is generally recognized as safe (GRAS) or meets one of the other exclusions from the food additive definition in 201(s). **All food additives and ingredients used in a licensed food establishment in North Dakota must comply with the law and must come from approved sources.**

Additives in food provide a variety of functions, such as preservatives to maintain or improve safety and freshness, nutrients such as vitamins and minerals, natural or artificial flavors and sweeteners to enhance taste, and emulsifiers, stabilizers, and thickeners to improve texture. Many products are approved by the FDA as an additive on a case-by-case basis for a specific use. For example, chlorella used as a color additive is prohibited, however, it is allowed as a replacement for cream, milk, eggs, and/or butter in small amounts. Activated charcoal is acceptable to use as a processing aid to filter water but is not allowed as a food additive.

Most ingredients and food that you purchase from a commercial supplier are GRAS. There is a list of GRAS substances (hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices) on the FDA website with names of the food items as well as how much can be added to food. If the substance is not generally recognized as safe, federal and state laws require scientific evidence to prove its safety.

What is a Dietary Supplement?

Dietary supplements are products (other than tobacco) intended to supplement the diet that contain one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or a combination of these (FD&C Act § 201(ff)). Dietary supplements are products intended for ingestion and are not for use as a conventional food or as a sole item of a meal or the diet and are labeled as dietary supplements. FDA does not approve dietary supplements or dietary ingredients, and these products do not require a premarket review or approval.

Retailers may sell packaged dietary supplements in their original, intact packaging, but they may not add them to food or beverages. The only exception to this rule is if ALL dietary ingredients listed on the supplement's label are determined to be GRAS. An example of a dietary supplement with dietary ingredients which are GRAS would be whey protein concentrate powder and therefore it may be added to food. Alternatively, ashwagandha is a dietary supplement which contains unapproved dietary ingredients and may not be added to food.

Although dietary supplements are not subject to pre-approval by the FDA, supplement manufacturers are required to register with the FDA to manufacture, process, pack, or hold food, including dietary supplements, for consumption, and the packaged supplement is required to be labeled.

Public Health Reasons

Food additives and any dietary ingredients that become components of conventional food, either directly or indirectly, used in excessive amounts or not as intended or approved, may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for additives and dietary ingredients must be supported by science that demonstrates its use meets the FDA's safety standard. The information must demonstrate that there is a reasonable certainty of no harm to consumers.

Food and color additives and dietary ingredients must be used in compliance with federal and state food laws and regulations. Such regulations are generally composed of three parts:

- The identity of the substance.
- Specifications including purity, or physical properties.
- Limitations on the conditions of use.

Food and color additives and dietary ingredients must comply with all three criteria to be allowed for use in a retail food establishment. The ingredient manufacturer may provide a letter of guaranty to assure that an ingredient is not adulterated or misbranded and to provide proof that their product is approved as an additive to be allowed for use in food.

Additional Information

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 (fda.gov/food/nutrition-food-labeling-and-critical-foods/questions-and-answers-health-claims-food-labeling).

For more additive information:

- Food Ingredient and Packaging Inventories (fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-inventories)
- Office of Food Additive Safety: premarkt@fda.hhs.gov

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