

MEMORANDUM

From: Steven B. Steinborn
Leigh G. Barcham

Date: November 11, 2015

Re: **FDA Issues Guidance on Fortification Policy**

The U.S. Food and Drug Administration (FDA) has issued guidance on the fortification of foods with essential nutrients, clarifying and reminding industry of the original policy issued in 1980. ^{1/} FDA's guidance addresses questions related to the fortification policy and consolidates information on fortification of various foods into a single document. This memorandum summarizes some of the key points in the guidance addressing the principles of the fortification policy, the foods and nutrients covered by the policy, claims associated with fortified foods, and FDA's enforcement of the policy.

Principles of the Fortification Policy

The general purpose of the fortification policy is to ensure the rational addition of essential nutrients to conventional foods and to discourage indiscriminate addition of nutrients to foods. For example, FDA explains that adding calcium to soy beverages is considered rational fortification because it provides a reasonable vehicle of fortification for people who are lactose intolerant or otherwise do not drink milk.

The guidance also sheds light on when it is permissible to fortify a food to make a health claim. Under FDA's regulation for health claims (21 C.F.R. § 101.14(e)(6)), the food must contain naturally 10 percent or more of the Reference Daily Intake (RDI) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed (RACC) before any nutrient may be added. If the food meets this requirement, a nutrient that is the subject of the health claim may be added to meet the health claim requirements. By way of example, FDA explains that when adding calcium to a conventional food such as orange juice to make a calcium and osteoporosis health claim, the food must already meet the general requirements of a health claim. Thus, the orange juice would be required to contain 10 percent or more of the Daily Reference Value of naturally occurring vitamin C.

^{1/} The four core principles that guide rational (i.e., lawful) fortification include: (1) to correct a dietary insufficiency; (2) to restore a food's nutrient levels to those prior to storage, handling, and processing; (3) to provide a balance of vitamins, minerals, and protein in proportion to the total caloric content of the food (i.e., nutrient-to-calorie balance); and (4) to prevent nutrient inferiority in a food that replaces a traditional food. The fortification policy is located at 21 C.F.R. § 104.20.

Foods Covered Under the Fortification Policy

The guidance also elaborates on the types of foods for which fortification is deemed inappropriate, including examples of foods that should not be fortified. The fortification policy expressly states that the fortification of fresh produce; meat, poultry, or fish products; sugars; and snack foods is not considered appropriate. FDA explains in the guidance that “snack foods” refers to “foods that are not naturally nutrient dense” such as cookies, candies, cakes, chips, and both sweetened and unsweetened beverages, including low-calorie and calorie-free snack foods. According to FDA, fortification of these types of snack foods could mislead consumers to believe that a substitution of naturally nutrient dense foods with a fortified snack food would ensure a nutritionally adequate diet.

Nutrients Covered Under the Fortification Policy

The guidance clarifies the nutrients that may be used and how to determine when fortification of a food with a particular nutrient is appropriate. Since FDA first established the fortification policy, the agency has added several essential nutrients to the list of vitamins and minerals in 21 C.F.R. § 101.9(c)(8)(iv), which lists the RDI for essential vitamins and minerals. FDA explains in the guidance that although the fortification policy does not reference all the vitamins and minerals listed in 21 C.F.R. § 101.9(c)(8)(iv), any of the nutrients assigned an RDI in this regulation may be added to foods if consistent with the fortification policy. Fortification is only appropriate for these essential vitamins and minerals and for potassium and protein; it is not appropriate for vitamins and minerals for which there is no RDI or established reference value (e.g., lycopene and lutein).

Various other conditions are identified to determine when fortification is appropriate. For example, nutrient addition is appropriate when the nutrient is added at a level to avoid excessive intake of that nutrient, taking into account the cumulative amounts of the nutrient from all dietary sources. When assessing excessive total intakes, the guidance directs food manufacturers to consult the upper levels of intake, including the tolerable upper intake levels (ULs), that the Institute of Medicine has established since FDA issued the original fortification policy.

Nutrient-to-Calorie Balance Principle

One of the principles of rational fortification outlined in the policy is to provide a balance of vitamins, minerals, and protein in proportion to the total caloric content of the food. This principle recognizes that sometimes the uses of new or unique products cannot be anticipated, and consequently the products cannot be categorized as substitutes or replacements for a particular food. Rather than developing a nutrient profile for all the foods the product might replace, the “nutrient-to-calorie balance” principle allows food producers to develop a profile that would sustain a balance in the average’s persons overall nutrient intake by relating nutrient content to caloric content, according to FDA.

FDA also identifies several circumstances when use of this principle would not support fortification of a food. Fortification is not appropriate, for example, for reformulated meal replacement products used for weight reduction to replace a traditional, higher-calorie meal. If a food substitutes for and resembles a traditional food, FDA also advises that it may be more appropriate to fortify the food under the “imitation principle” detailed in 21 C.F.R. § 104.20(e).

Claims Regarding Fortification

A number of different defined nutrient content claims may be used to highlight a fortified nutrient (e.g., “fortified,” “enriched,” “added,” “more,” “plus”). The guidance also identifies the specific claims laid out in the policy that may be used when a food is fortified under the restoration principle or the nutrient-to-calorie balance principle.

- For foods fortified under the restoration principle: “Fully restored with vitamins and minerals” or “fully restored with vitamins and minerals to the level of unprocessed _____.”
- For foods fortified under the nutrient-to-calorie balance principle: “Vitamins and minerals (and “protein” when appropriate) are added in proportion to caloric content.”

Enforcement of the Fortification Policy

Although the fortification policy is non-binding, since its adoption FDA has incorporated the policy into the nutrient content claim regulations for “more” and its synonyms (21 C.F.R. § 101.54(e)) and for “healthy” and related terms (21 C.F.R. § 101.65(d)(iv)). Thus, if a food bearing one of these nutrient content claims has been fortified in a manner inconsistent with the fortification policy, FDA may issue a Warning Letter and take enforcement action.

* * *

Please let us know if you have questions or if we can be of any further assistance.