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Questions and Answers on FDA's Fortification Policy

Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

November 2015

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Questions and Answers on FDA's Fortification Policy[1]
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I. Introduction

The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. Adding nutrients to specific foods is an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or underfortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims on certain foods.

On January 25, 1980, FDA (we) published our fortification policy entitled "Nutritional Quality of Foods; Addition of Nutrients" in the *Federal Register* (45 FR 6314) and included the policy in the *Code of Federal Regulations* (21 CFR 104.20). The fortification policy discourages indiscriminate addition of nutrients to foods.

Since the publication of the policy, we have received numerous questions on using the principles within this policy from the food industry, other federal agencies, academia, and others. This guidance is intended to clarify the existing policy, especially those matters we received questions on, and to remind manufacturers of this policy. This policy addresses when foods may be fortified, and it urges you, the

[1] This guidance has been prepared by the Nutrition Programs Staff and the Food Labeling and Standards Staff in the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration.

manufacturer, to follow the principles of the policy if you elect to add nutrients to a food for human consumption.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

II. Background

FDA's fortification policy establishes a uniform set of principles to serve as a model for the rational addition of essential nutrients to foods. The principles of rational fortification are to:

- Correct a dietary insufficiency (21 CFR 104.20(b));
- Restore nutrient levels to those prior to storage, handling, and processing (restoration principle) (21 CFR 104.20(c));
- Provide a balance of vitamins, minerals, and protein in proportion to the total caloric content of the food (nutrient-to-calorie balance principle) (21 CFR 104.20(d)); and
- Prevent nutrient inferiority in a food that replaces a traditional food in the diet (21 CFR 104.20(e)).

For more information about applying these principles, please see the "Principles of the Fortification Policy for Specific Purposes" below.

III. Questions & Answers

A. Overarching Principles and Applicability of the Fortification Policy

A1. What is the general purpose of FDA's fortification policy?

This policy establishes a uniform set of principles concerning the nutrient fortification of foods, which manufacturers are urged to follow if they elect to add nutrients to a manufactured or processed food. As stated in the background, the principles of rational fortification expressed in the policy are to: correct a dietary insufficiency, restore nutrient levels to those prior to storage, handling, and processing, provide a balance of vitamins, minerals, and protein in proportion to the total caloric content of the food, and prevent nutrient inferiority in a food that replaces a traditional food in the diet. The principles are a model for the rational

addition of essential nutrients to conventional foods to preserve a balance of nutrients in the diet of consumers in the United States. This policy is based on United States dietary practices and nutritional needs and may not be applicable in other countries. This policy discourages the indiscriminate addition of nutrients to foods.

A2. What is an example of a rational addition?

Adding calcium to soy beverages is a rational addition because it provides a reasonable vehicle for people who do not drink milk, such as those who are lactose intolerant, but do want to obtain calcium, an essential mineral.

A3. Should I follow all of the principles listed in the fortification policy?

No. You should follow the principles that relate to your nutrient objectives. For example, if a food loses a nutrient during processing, then you should follow the restoration principle to restore that nutrient to the original level before loss in processing (21 CFR 104.20(c)). See section on "Principles of the Fortification Policy for Specific Purposes."

A4. Does the fortification policy apply to animal foods?

No. The principles of the fortification policy apply to conventional foods consumed by humans.

A5. Does the fortification policy apply to infant formula and dietary supplements?

No. The fortification policy does not apply to infant formula or dietary supplements. For information about regulations for the addition of nutrients to infant formula, see 21 CFR 107.100. For information about the addition of nutrients to dietary supplements, see http://www.fda.gov/Food/DietarySupplements.

A6. Is nutrient fortification of foods mandatory in the United States?

With the exception of some standardized foods, fortification is not mandatory in the United States. Foods subject to certain standards of identity may be required to be fortified with certain vitamins and minerals. For example, enriched flour must contain particular levels of thiamin, riboflavin, niacin, iron, and folic acid specified in 21 CFR 137.165. However, you are not required to enrich your products. For every standard of identity for an enriched product, we have a corresponding standard of identity for the unenriched product.

A7. What is voluntary nutrient fortification of foods?

In general, voluntary fortification refers to adding nutrients to foods that do not have a standard of identity for enriched products. Voluntary fortification would apply to the following types of foods:

- Foods that do not have a standard of identity – If you fortify foods without a standard of identity, you should follow the fortification policy in 21 CFR 104.20.
- Foods that have a standard of identity (for example, orange juice) but whose standard does not include the addition of a particular nutrient – If you fortify these foods, you must follow
  - The requirements in 21 CFR 130.10 ("Requirements for foods named by use of a nutrient content claim and a standardized term" referred to as the generic standard) at levels for the additional nutrient consistent with 21 CFR 101.54(e) claim (the definition for "more"). This claim requires adherence to the fortification policy (21 CFR 101.54(e)).
- Foods bearing the term "healthy" to which a nutrient has been added to meet the requirement that the food contain 10 percent or more of the Daily Value per reference amount of vitamin A, vitamin C, calcium, iron, protein, or fiber (21 CFR 101.65(d)) – These foods must be fortified under the requirements of the fortification policy.

A8. Does the fortification policy apply to both voluntary and mandatory fortification?

Yes. We have used the principles in the fortification policy to issue regulations such as the standards of identity that require the addition of folic acid to various enriched grain products (21 CFR Parts 136, 137. 139). You should also follow the fortification policy described in this guidance for voluntary fortification of foods.

A9. Can I fortify products in order to make a health claim?

Under the regulation for health claims (21 CFR 101.14(e)(6)), the food must naturally contain 10 percent or more of the Reference Daily Intake (RDI) of the Daily Reference Value (DRV) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition. This does not pertain to dietary supplements or exemptions made for specific health claims. However, if a food meets this requirement, you may add the nutrient or substance that is the subject of the health claim to meet the requirements of the health claim. An example would be adding calcium to a conventional food such as orange juice when making the calcium and osteoporosis health claim (21 CFR 101.72). The conventional food must already meet the general requirements of a health claim under 21 CFR 101.14. In this example, the food (orange juice) would be required to contain 10 percent or more of the Daily Reference Value of naturally occurring vitamin C.

B. Foods Covered Under the Fortification Policy

B1. What foods are covered under the fortification policy?

The fortification policy applies to certain conventional foods for human consumption. It does not apply to animal foods, infant formulas, or dietary supplements (see questions A4 and A5). The policy applies to certain conventional foods with or without an FDA food standard of identity regulation.

B2. Is it appropriate to use any conventional food (with exception of infant formula) as a vehicle of fortification for human use?

Under our fortification policy, it is not appropriate to fortify certain foods, such as fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. See also questions B3 and B4.

Customary dietary practice firmly establishes the use of meat, poultry, or fish products and fresh produce, and the public understands the role of these products in a balanced diet. Because this policy is a guideline for the rational addition of nutrients to food, we see no reason to add nutrients to these foods.

In the fortification policy, snack foods refer to foods that are not naturally nutrient dense; examples include cookies, candies, cakes, chips, and carbonated beverages (both sweetened and unsweetened). Fortification of these types of snack foods could mislead consumers to believe that substitution of naturally nutrient dense foods with fortified snack foods would ensure a nutritionally adequate diet.

Moreover, the fortification of such snack foods would disrupt public understanding about the nutritional value of individual foods and thereby promote confusion among consumers, making it more difficult for them to construct diets that are nutritionally adequate.

For further discussion on our policy regarding fortification of snack foods, see the preamble of the final rule at 45 FR 6314 at 6315.

B3. Is it appropriate to fortify unsweetened carbonated beverages and low-calorie and calorie-free snack foods?

No. Under our fortification policy, it is not appropriate to fortify unsweetened carbonated beverages and low-calorie and calorie-free snack foods (e.g., low calorie or fat free cookies).

B4. Is it appropriate to add vitamins and minerals to alcoholic beverages?

No. Under our fortification policy, we do not consider it appropriate to add vitamins and minerals to alcoholic beverages.

B5. Why should I follow FDA's fortification policy for meat and poultry that are under the U.S. Department of Agriculture's (USDA) jurisdiction?

The USDA Food Safety and Inspection Service (FSIS) has requirements on labeling meat and poultry products (see http://www.fsis.usda.gov/shared/PDF/Nutrients_Meat_&_Poultry.pdf). FSIS cites our fortification policy in its label requirements. As stated in question B2, we do not recommend that you fortify meat and poultry products. If you need more information on fortifying meat and poultry products that FSIS regulates, consult with FSIS.

Foods with Standards of Identity Used as Vehicles of Fortification

B6. How do FDA's food standards of identity regulations relate to fortification?

FDA's regulations on food standards of identity in 21 CFR parts 130 through 169 specify which ingredients a food product must contain and how to make the product in order to market it under a specific name, or statement of identity. On occasion, food standards of identity have served as a means to improve the overall nutritional quality of the food supply and to meet a demonstrated public health need. For example, adding folic acid to certain standardized foods, such as enriched grain products, is required so that the resulting food product may help to reduce the risk of neural tube birth defects in infants (21 CFR 172.345).

B7. What are some examples of standardized foods that are fortified?

- Enriched cereal flours and related products such as enriched flour (21 CFR 137.165);
- Enriched bakery products such as enriched bread, rolls, and buns (21 CFR 136.115);
- Enriched macaroni products (21 CFR 139.115);
- Margarine, mandatory addition of vitamin A and optional addition of vitamin D (21 CFR 166. 110); and
- Milk, optional addition of vitamins A and D (21 CFR 131.110).

B8. What are the nutrient requirements for standardized cereal flours and other standardized bakery products that are labeled as being enriched?

Standards for these enriched products require that they contain specified amounts of thiamin, riboflavin, niacin, iron, and folic acid. We also have provisions for the optional addition of calcium and vitamin D to some of these products. Details on

specific provisions of each standard of identity are provided in 21 CFR parts 130 through 169.

B9. What is an example of a conventional food that is not a standardized food that may be fortified?

Though not covered under a standard of identity regulation, manufacturers may add iodine, in the form of cuprous iodide (21 CFR 184.1265) or potassium iodide (21 CFR 184.1634), to salt or table salt for human food use. The term "iodized salt" or "iodized table salt" is designated as the name of salt that has added iodine. The statement "This salt supplies iodide, a necessary nutrient" must also appear on the label of packages intended for retail sale (21 CFR 100.155). However, you are not required to add iodine to salt or table salt. Retail packages of salts without iodine must bear the statement "This salt does not supply iodide, a necessary nutrient" (21 CFR 100.155).

C. Nutrients Covered Under the Fortification Policy

C1. What nutrients are covered under the fortification policy?

Only essential nutrients are within the scope of our fortification policy. The term "essential nutrient" under the fortification policy refers to the vitamins and minerals assigned Reference Daily Intakes (RDIs) listed in 21 CFR 101.9(c)(8)(iv), as well as protein and potassium that have daily reference values (DRVs) (21 CFR 101.9(c)(9) or 21 CFR 104.20(d)(3)).

In addition, the source of the essential nutrient must be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act. For conventional foods, this evaluation involves considering whether the nutrient added to the food is generally recognized as safe (GRAS) under the conditions of its intended use, approved as a food additive, or authorized by a prior sanction issued by FDA (21 CFR parts 182, 184 and 172). The food additive regulations or GRAS status of some nutrients may also limit which foods may be fortified and at what level. For example, the food additive regulation on folic acid (21 CFR 172.345) and vitamin D (21 CFR 172.379; 21 CFR 172.380) stipulates which foods may be fortified and at what level.

C2. Does the fortification policy apply to all of the essential vitamins and minerals listed in 21 CFR 101.9(c)(8)(iv)? If so, why are they not listed under 21 CFR 104.20(d)(3)?

The fortification policy applies to all essential vitamins and minerals listed in 21 CFR 101.9(c)(8)(iv).

When we established the fortification policy in 1980, we anticipated that additional essential nutrients would be added to the list of vitamins and minerals in 21 CFR 101.9(c)(8)(iv) and would be eligible for the rational fortification of food. Therefore, 21 CFR 104.20(a) states, in part, that:

> It is reasonable to anticipate that the RDIs as delineated in 21 CFR 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific RDI's as improved knowledge about human nutrient requirements and allowances develops.

In 1980, the essential vitamins and minerals listed in 21 CFR 104.20(d)(3) were the same as those listed in 21 CFR 101.9(c)(7)(iv) (38 FR 2125; January 19, 1973). At that time, RDIs for several vitamins and minerals that are now considered essential had not been established (for example, selenium and chromium). In 1995, we amended the list of essential vitamins and minerals to include vitamin K, manganese, selenium, chromium, molybdenum, and chloride and provided RDIs under 21 CFR 101.9(c)(8)(iv) (60 FR 67164; December 28, 1995). These nutrients may be rationally added to food under the fortification policy. As we add other essential vitamins and minerals to 21 CFR 101.9(c)(8)(iv), they will also be covered under the fortification policy unless other regulations prohibit the addition of the nutrients to certain foods.

C3. Are nutrients that do not have an RDI or an established reference value (for example, lycopene and lutein) covered under this policy?

No. Only essential nutrients with an RDI (21 CFR 101.9(c)(8)(iv)), as well as potassium and protein (21 CFR 101.9(c)(9)) are covered under this policy.

C4. When is it appropriate to add an essential nutrient to a food under the fortification policy (21 CFR 104.20(g))?

In addition to the circumstances permitting fortification discussed throughout this document, the general requirements in 21 CFR 104.20(g) applies to all types of nutrient additions under the fortification policy. Before adding a nutrient to a food, you should ensure the nutrient meets all of the following conditions:

- The nutrient is stable in the food under customary conditions of storage, distribution, and use.
- The nutrient is physiologically available from the food.
- The nutrient is added at an appropriate level to avoid excessive intake of that nutrient, considering cumulative amounts from all sources in the diet. To assess excessive total intakes of essential vitamins and minerals and to estimate safe limits of addition of essential nutrients, you should use upper levels of intake when available, such as the tolerable upper intake level (UL) established by the

Institute of Medicine (IOM). After we established the fortification policy, the IOM established ULs for a number of nutrients. The ULs can be considered in assessing excessive intake in different subpopulations (Ref 1).

- The nutrient is suitable for its intended purpose and complies with the Federal Food, Drug, and Cosmetic Act and regulations governing the safety of substances in food.

D. Principles of the Fortification Policy for Specific Purposes

D1. What is meant by the principle that permits the addition of nutrients to a food to correct a dietary insufficiency (21 CFR 104.20(b))?

This principle means that you can add essential nutrients (see question C1 for definition of essential nutrients) to a food to correct a dietary insufficiency or meet a demonstrated public health need if the scientific community recognizes the dietary insufficiency and knows the deficiency results in a nutritional deficiency disease.

D2. Who should identify nutritional problems, the population groups affected by these problems, and the identity of suitable foods that may act as vehicles for adding appropriate nutrients to address these problems?

Identifying nutritional problems and implementing measures to correct these problems involve the combined efforts of many participants. FDA serves as a focal point for identifying public health problems with respect to fortifying and labeling foods that it regulates. In conjunction with other government agencies, research groups, educational institutions, and informed consumer groups, FDA participates in the collection and exchange of information relating to nutritional problems. We urge you to consult us if you are considering adding nutrients to food based on this principle. (For contact information, see the information on the title page of this guidance document.)

D3. What is an example of a nutrient addition to the U.S. food supply for public health purpose?

Requiring folic acid in standardized enriched grain products is an example of a nutrient addition for a public health purpose. In September 1992, the United States Public Health Service (PHS) recommended that all women who are capable to become pregnant consume 400 micrograms of folic acid daily to reduce their risk of having a newborn affected by neural tube defects. Since 1998, in keeping with the recommendations of PHS, FDA has required that folic acid be added to standardized enriched grain products (21 CFR Parts 136, 137 and 139). The rationale for fortifying standardized enriched cereal grain products as a vehicle of fortification was that most women consume these products. Thus, fortification of these products

would lead to increased folic acid intake of most women without requiring a change in their dietary patterns.

In general, before FDA requires fortification of the food supply with a nutrient (for example, folic acid), we perform a dietary modeling exercise of current dietary intakes to evaluate possible fortification levels for the target population (women of childbearing age). The intake levels must be effective for the target population and safe for the overall population.

Before requiring fortification of enriched cereal grains with folic acid, FDA estimated the effects of fortification on the target population and the general population. Estimated distributions of current total daily folate intake (conventional foods plus supplements) and projected intakes with folic acid fortification from a national food consumption survey were created for eight age groups for males and females.[2]

Based on the modeling exercise and rulemaking procedures, we approved fortification of enriched grains with folic acid at specified levels (21 CFR parts 136, 137, and 139), as well as under the food additive regulation (21 CFR 172.345). Under the food additive regulation, you can add folic acid to enriched grain products, breakfast cereals, corn grits, meal replacement products, infant formula, and foods for special dietary use. The addition of folic acid to standardized enriched grains has led to increased folic acid intake, improved levels in serum and red blood cells, and decreased prevalence of neural tube birth defects in the United States (Refs.2 and 3).

D4. What does the restoration principle in 21 CFR 104.20(c) mean?

The restoration principle means you can add nutrients to a food to restore such nutrients to levels representative of the food prior to storage, handling, and processing, when adequate scientific documentation shows the nutrient to have been lost in a measurable amount (that is, at least 2 percent of the RDI or Daily Reference Value (DRV) per serving) in storage, handling, and processing. You should use this principle when:

- Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of the nutrients;
- All nutrients that are lost in measurable amounts are restored and all ingredients of the food product that contribute nutrients are considered in determining restoration levels;
- No other Federal regulation requires or prohibits nutrient additions to the food;

[2] See the final rule of March 5, 1996, for more information on fortification with folic acid (61 FR 8781–8807).

- The food has not been fortified in accordance with a Federal regulation that permits voluntary nutrient additions.

D5. Should I restore only one or all nutrients that were lost during storage, processing, and handling?

If you use the restoration principle, then you should restore all essential nutrients (see question C1 for definition of essential nutrients) lost at measurable amounts (at least 2 percent of the RDI or DRV per serving) during storage, processing, and handling. Partial restoration may result in restoring only those nutrients that are least expensive, technologically easiest to add, or required to be listed in nutrition labeling. Therefore, partial restoration may contribute to nutrient imbalance in the food supply.

D6. What is the nutrient-to-calorie balance principle in 21 CFR 104.20(d)?

This principle means you may add nutrients listed in 21 CFR 101.9(c)(8)(iv) as well as protein and potassium under 21 CFR 101.9(c)(9) to a food in proportion to the food's total caloric content, to balance the vitamin, mineral, and protein content if the following apply:

- A normal serving of the food contains at least 40 calories, (that is, 2 percent of 2,000 calories as a daily reference amount);
- Based on the 2,000 calorie daily reference amount, the food contains each of the listed nutrients in 21 CFR 101.9(c)(8)(iv), as well as protein and potassium under 21 CFR 101.9(c)(9), at a level equal to at least 1/20th of the RDI per 100 calories of food; and
- No other Federal regulation for the food or class of food requires, permits, or prohibits nutrient additions.

D7. Why did FDA establish the nutrient-to-calorie balance principle?

We established this principle to provide a general basis for fortifying foods when no specific regulation exists, such as a food standard of identity or nutritional quality guideline under 21 CFR 104.47. In the absence of a specific regulation governing the enrichment of a food, the nutrient-to-calorie balance principle provides a suitable basis for adding nutrients to fabricated foods that may replace large portions of the total diet.

In general, when the specific use of new or unique products cannot be predicted, it is not possible to anticipate a specific and limited nutrient content or profile. Therefore, when products cannot be categorized as substitutes or replacements for a particular food and you elect to add nutrients to such products, the nutrient additions should conform to a profile reflecting all the foods that the product might substitute for or replace in the diet. Because it is impractical to develop a profile for each food,

a logical alternative is a profile that would sustain a balance in the average person's overall nutrient intake by relating nutrient content to caloric content.

For further discussion on the nutrient-to-calorie balance principle, see the final rule preamble at 45 FR 6314 at 6317.

D8. When is the use of the nutrient-to-calorie balance principle not appropriate?

Adding nutrients to foods based on the nutrient-to-calorie balance principle is not appropriate under any of the following conditions:

- The nutrient addition or composition of a food or class of foods has already been established by an applicable Federal regulation, such as a standard of identity.
- A formulated meal replacement product for use in weight reduction replaces a traditional, higher calorie meal. If a manufacturer fortifies the meal replacement based on its caloric contribution, the meal replacement would not always provide the appropriate amounts of necessary vitamins and minerals that a traditional, higher calorie meal normally provides.
- The food substitutes for and resembles a traditional food. It may be more appropriate to fortify a food under the "imitation principle" described in question D9.

D9. What does 21 CFR 104.20(e) mean when it states, "a nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with § 101.3(e)(2) of this chapter"?

Some foods are designed to replace traditional foods, such as an almond spread for an almond butter. Absent a specific regulation, such as a common or usual name regulation (21 CFR part 102), a food that substitutes for and resembles another food must provide essential nutrients at levels nutritionally equivalent to the food it resembles or must bear an "imitation" label in accordance with 21 CFR 101.3(e).

To avoid labeling the substitute food as imitation based on nutritional inferiority, you must fortify the substitute food with the same amount of any nutrients, other than fat or calories that are present in the traditional food in a measurable amount (21 CFR 101.3 (e)). A measurable amount of an essential nutrient is as follows:

- 2 percent or more of the DRV of protein (101.9(c)(7)(iii)) and of potassium (21 CFR 101.9(c)(9)) per reference amount customarily consumed (RACC);

- 2 percent or more of the RDI of any vitamin or mineral listed under 21 CFR 101.9(c)(8)(iv) per RACC, except for selenium, molybdenum, chromium, and chloride.

Alternatively, you must label the food by a different name, such as "almond spread" rather than "almond butter." See 21 CFR 101.3(e) for details on the provisions for "imitation" labeling.

D10. What does the statement "Nutrient(s) may be added to foods as permitted or required by applicable regulation established elsewhere in this chapter" in 21 CFR 104.20(f) mean?

This statement means you can add essential nutrients to foods according to existing regulations. We based the regulations on adding nutrients to foods on the best available scientific data on food consumption patterns, nutritional needs, and dietary habits of the general population. The applicable regulations are those pertaining to a common or usual name for specific nonstandardized foods (21 CFR part 102), food standards of identity (21 CFR parts 130 through 169), and specific nutritional quality guidelines (21 CFR 104.47).

E. Claims and Other Statements on the Food Label

E1. What requirements pertain to claims and other statements on the food label of fortified foods (21 CFR 104.20(h))?

As explained in 21 CFR 104.20(h), any labeling claims or statements about the addition of a vitamin, mineral, or protein to a food shall be made only if the following apply:

- The claim or statement is not false or misleading in accordance with the provisions in section 403 of the Federal Food, Drug, and Cosmetic Act; and
- The claim or statement complies with any applicable regulations such as those in the food labeling regulations (21 CFR part 101).

E2. How does FDA regard the terms "fortified" and "enriched" on the food labels (21 CFR 104.20(h))?

The terms "enriched," "fortified," or similar terms may be used interchangeably to indicate that one or more essential nutrients were added to a food unless an applicable Federal regulation requires the use of specific words or statements.

Since FDA issued regulations under the Nutrition Labeling and Education Act of 1990, "enriched" and "fortified" as well as "added," "plus," "extra," and "more" are defined nutrient content claims. In general, labeling bearing these terms must comply with the definition for "more" (21 CFR 101.54(e)). However, if a food standard of identity exists for a particular food and the claim is part of the food's name, you must use the term identified in the regulation. Examples of a name required by a standard of identity include enriched bread, rolls, and buns (21 CFR

136.115) and enriched flour (21 CFR 137.165). An example of a standardized food that must use a particular claim is "milk vitamins A and D added" (21 CFR 131.110). See also questions E4 and E5.

E3. Can I use alternate terms, such as fortified, interchangeably for standardized foods?

No. You must use the name prescribed in the regulations for the standardized food (Section 403 (g) of the Federal Food, Drug, and Cosmetic Act). For example, you cannot substitute the term "fortified flour" for "enriched flour."

E4. What are examples of acceptable labeling claims I may use in relation to the fortification policy (21 CFR 104.20(h))?

In addition to the nutrient content claims "added," "enriched," "extra," "fortified," "more," and "plus," you may use the following labeling claims:

- "Fully restored with vitamins and minerals" or "fully restored with vitamins and minerals to the level of unprocessed ___" (fill the blank in with the common or usual name of the food) to describe foods fortified in accordance with the restoration principles in 21 CFR 104.20(c); and
- "Vitamins and minerals (and "protein" when appropriate) added are in proportion to caloric content" to describe foods fortified in accordance with the nutrient-to-calorie balance principles in 21 CFR 104.20(d).

As discussed in questions E2 and E3, you can use the term "enriched," "fortified," "added," or similar terms interchangeably, when labeling claims are allowed, to indicate the addition of one or more vitamins, minerals, or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements. For example, 21 CFR 131.110(e)(1) for milk states:

> The following terms shall accompany the name of the food…(i) if vitamins are added, the phrase "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added," or "vitamin A and D" or "vitamins A and D added"….

In this case and in similar cases, you must use only the terms specified in the regulation.

E5. Is it appropriate to make a claim or statement about a food that is fortified to prevent nutritional inferiority (21 CFR 104.20(i))?

No. According to 21 CFR 104.20(i), it is inappropriate to make any claim or statement (other than in the ingredient list) concerning nutrients that are added to foods to prevent nutritional inferiority (see 21 CFR 101.3(e)). Doing so may result in a substitute food appearing to be superior to the food that it resembles because a

claim or statement suggests that the food contains additional nutrients compared to the traditional food. See question D10.

F. Enforcement of the Fortification Policy Incorporated into Regulations

F1. How does FDA enforce the fortification policy that has been incorporated into regulations?

Although this policy is primarily used as guidance, we have incorporated the provisions of the fortification policy into the following two nutrient content claim regulations that have the force and effect of law:

- "More" and its synonyms "fortified," "enriched," "added," "extra," and "plus" (21 CFR 101.54(e)); and
- "Healthy" and related terms such as "healthful" and "healthier" (21 CFR 101.65(d)(iv)).

Consequently, FDA may issue a warning letter and take enforcement action if a marketed food bearing one or more of these nutrient content claims contains a nutrient addition that is inconsistent with the fortification policy as incorporated into the regulations noted above. Nevertheless, FDA strongly encourages you to follow these fortification guidelines regardless of whether any claims appear on the label or in labeling.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. Institute of Medicine, Dietary Reference Intakes- A risk assessment model for establishing upper intake levels for nutrients. National Academy Press. 1998. Washington D.C.

2. Pfeiffer CM, Johnson CL, Jain RB, Yetley EA, Picciano MF, Rader JI, Fisher KD, Mulinare J, Osterloh JD. Trends in blood folate and vitamin B-12 concentrations in the United States, 1988–2004. Am J Clin Nutr. 2007. 86:718-727.

3. Centers for Disease Control and Prevention. Spina bifida and anencephaly before and after folic acid mandate–United States, 1995–1996 and 1999–2000. 2004. Report No 53.