

Guidance for Industry

Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements

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You may submit written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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Table of Contents

- I. Introduction**
- II. Background**
- III. Discussion**
 - A. Conventional Foods**
 - B. Dietary Supplements**
- IV. Conclusion**
- V. References**

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

We are issuing this guidance for two purposes. The first purpose of the guidance is to remind manufacturers and distributors of conventional foods about the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding substances added to conventional foods, including beverages. “Substance” is defined in FDA’s food additive regulations to include foods and food components consisting of one or more ingredients (21 CFR 170.3(g)). Thus, a “substance” for purposes of the regulations and this guidance may be a food (e.g., an apple) that can be eaten on its own as well as used as an ingredient in other foods, or it may be a food that is used only as a component of other foods (e.g., flour). A second purpose of the guidance is to remind dietary supplement manufacturers and distributors that the same requirements apply to certain substances that are added to dietary supplements -- namely, those that are not dietary ingredients as defined in section 201(ff)(1) of the FD&C Act (21 U.S.C. § 321(ff)(1)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's 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 Agency guidance means that something is suggested or recommended, but not required.

In this guidance, “we” refers to FDA and “you” refers to manufacturers and distributors of foods, including beverages and, where applicable, dietary supplements (see Section III.B).

¹ This guidance has been prepared by the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Background

We have seen a growth in the marketplace of beverages and other conventional foods that contain novel substances, such as added botanical ingredients or their extracts. Some of these substances have not previously been used in conventional foods and may be unapproved food additives. Other substances that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels, or in new beverages or other conventional foods. This trend raises questions regarding whether these new uses are unapproved food additive uses.

III. Discussion

A. Conventional Foods

If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition,² it is a food additive. Many substances intentionally added to beverages and other conventional foods are food additives. Food additives require premarket approval based on data demonstrating safety. Usually, these data are submitted to us in a food additive petition, although we may also approve a food additive on our own initiative without first receiving a petition. We issue food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used. Any unapproved food additive used in a beverage or other conventional food causes the food to be adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)). Adulterated foods cannot be legally imported or marketed in the United States.

If a substance is GRAS under the conditions of its intended use in food, it is exempt from the definition of a food additive, and thus, from pre-market approval. (See section 201(s) of the FD&C Act (21 U.S.C. § 321(s))). For a particular use of a substance to be GRAS, there must be both evidence of safety and a basis to conclude that this evidence is generally known and accepted by qualified experts. In other words, the GRAS standard first requires that the scientific evidence about the substance establish that the intended use of the substance is safe; i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use (21 CFR 170.3(i)). In addition, under the second part of the GRAS standard, the scientific evidence to establish the safety of the substance for its intended use must be generally available, and there must be a basis to conclude that consensus exists among qualified experts about the safety of the substance for its intended use (see 21 CFR 170.30(a)-(c)).

² Under section 201(s) of the FD&C Act (21 U.S.C. § 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a “prior sanction” (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act; (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.

We are concerned that some of the novel substances that are being added to conventional foods, including beverages, may cause the food to be adulterated because these added substances may not be GRAS for their intended use and are not being used in accordance with a food additive regulation prescribing conditions of safe use. In addition, some substances that have been present in the food supply for many years are now being added to conventional foods at levels in excess of their traditional use levels or in new types of conventional foods. This trend raises questions as to whether these higher levels and other new conditions of use are safe.

B. Dietary Supplements

Section 201(s) of the FD&C Act (21 U.S.C. § 321(s)) exempts dietary ingredients used in dietary supplements from the food additive definition. Although a dietary ingredient used in a dietary supplement must not adulterate the supplement under section 402(f) of the FD&C Act (21 U.S.C. § 342(f)), it does not have to be GRAS for its intended use in the supplement. However, other ingredients intended for use in dietary supplements, such as binders, excipients, and fillers, are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, non-dietary ingredients added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for their intended use (unless they qualify for another exception to the food additive definition).³

IV. Conclusion

It is your responsibility to ensure that substances added to foods you manufacture or distribute, including non-dietary ingredients in dietary supplements, comply with all applicable regulatory requirements for substances added to food. The “Ingredients, Packaging and Labeling” page on FDA’s Web site (Ref. 1) includes links to regulatory requirements and recommendations that apply to such substances.

V. References

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

1. FDA. [Ingredients, Packaging & Labeling](http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm). Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm>.

³ See list in footnote 2.