

# Guidance for Industry

## Standard of Identity for White Chocolate

### Small Entity Compliance Guide

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**U.S. Department of Health and Human Services**  
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## **Guidance for Industry<sup>1</sup> Standard of Identity for White Chocolate Small Entity Compliance Guide**

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### **I. Introduction**

On October 4, 2002, FDA published a final rule in the Federal Register that established a standard of identity for white chocolate (67 FR 62171). The final rule became effective on January 1, 2004. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This guidance document restates in plain language the legal requirements set forth in 21 CFR 163.124 concerning the standard of identity for white chocolate. This regulation is binding and has the full force and effect of law.

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

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<sup>1</sup> This guidance has been prepared by the Food Labeling and Standards Staff in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

## **II. Questions and Answers**

1. Why did FDA establish a standard of identity for white chocolate?

FDA established a standard of identity for white chocolate in response to petitions filed separately by the Hershey Foods Corporation and by the Chocolate Manufacturers Association of the United States of America.

2. What is the composition of white chocolate?

White chocolate is the solid or semiplastic food prepared by mixing and grinding cocoa butter with one or more of the optional dairy ingredients listed in 21 CFR 163.124(b)(2) (see question 3 below) and one or more optional nutritive carbohydrate sweeteners. It contains a minimum of 20 percent cocoa butter, a minimum of 14 percent of total milk solids, a minimum of 3.5 percent milkfat, and a maximum of 55 percent nutritive carbohydrate sweeteners. (21 CFR 163.124)

3. What are the optional ingredients permitted in white chocolate?

White chocolate may contain nutritive carbohydrate sweeteners; dairy ingredients (cream, milkfat, butter, milk, dry whole milk, concentrated milk, evaporated milk, sweetened condensed milk, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk, concentrated buttermilk, dried buttermilk, and malted milk; a minimum of 1.5 percent emulsifying agents; spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried cereal extract, salt, and other seasonings that

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do not imitate the flavor of chocolate, milk, or butter; antioxidants; and whey or whey products at a minimum level of 5 percent by weight) (21 CFR 163.124 (b)).

4. What is the appropriate name for a white chocolate product?

The label must bear the name “white chocolate” or “white chocolate coating”, whichever is appropriate (21 CFR 163.64(c)).

5. What must appear on the label if one or more of the spices, flavorings, or seasonings are added to a white chocolate product?

When one or more of the spices, flavorings, or seasonings permitted by the standard are used, the label must bear an appropriate statement, e.g., “Spice added”, “Flavored with \_\_\_\_\_”, or “With \_\_\_\_\_ added”, the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used (21 CFR 163.124(c)).

6. May products that are made in accordance with the standard of identity for white chocolate, labeled with names other than “white chocolate”, e.g., “white confection”, continue to bear these names?

No, products that are made in accordance with the standard of identity for white chocolate must be named “white chocolate” or “white chocolate coating”, whichever is appropriate.

7. What are the labeling requirements for declaring ingredients in white chocolate?

Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101 and 21 CFR 130 (21 CFR 163.124(d)).

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8. Does this standard of identity apply to both domestic and imported products?

Yes, the standard of identity for white chocolate, like all regulations for food sold in interstate commerce, applies to both domestic and imported products.

9. Can States establish standards of identity for white chocolate that differ from 21 CFR 163.124?

Section 403A of the Federal Food, Drug, and Cosmetic Act prohibits States from establishing standards of identity that differ from Federal standards unless exempted by regulation following the submission of a petition.