Contains Nonbinding Recommendations

Labeling of Infant Formula: Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
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Labeling of Infant Formula: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration ("FDA" or "we") is publishing this reminder to infant formula manufacturers and distributors ("you") about certain labeling requirements for infant formula products. While this guidance provides information about the labeling requirements for infant formula products generally, we are concerned particularly about the number of infant formula products that bear the same or similar statements of identity but are different in composition or intended use. We have also noticed an increased use of nutrient content claims that render products misbranded under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance provides information that can help you understand and comply with relevant labeling requirements.

This guidance does not provide an exhaustive list of all regulations covering the labeling of infant formula. We encourage you to review your product labels to ensure they comply with FDA's regulations, especially—but not limited to—the regulations discussed in this guidance. We also encourage you to refer to our guidance documents at www.fda.gov/FoodGuidances for additional information.

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

[1] This guidance has been prepared by the Division of Food Labeling and Standards, Office of Nutrition and Food Labeling, in the Center for Food Safety and Applied Nutrition, at the U.S. Food and Drug Administration.

II. Statement of Identity

FDA regulates the statement of identity used on food labels, including infant formula labels. Section 403(i)(1) of the FD&C Act (21 U.S.C. 343(i)(1)) requires that labels bear the common or usual name of the food. The regulations governing the statement of identity of food products can be found in title 21 of the *Code of Federal Regulations* (21 CFR), § 101.3 and part 102.

Under applicable law, the principal display panel[2] (PDP) of a packaged food must bear, as one of its principal features, a statement of the identity of the commodity (21 CFR 101.3(a)). Under 21 CFR 101.3(b), the statement of identity must be expressed in terms of:

- The name specified in or required by any applicable Federal law or regulation (21 CFR 101.3(b)(1));
- The common or usual name of the food (21 CFR 101.3(b)(2)); or
- An "appropriately descriptive term," or when the nature of the food is obvious, a fanciful name commonly used by the public for such food" (21 CFR 101.3(b)(3)).

In addition, if you market a food in various optional forms, e.g., "powder" or "liquid concentrate," you must include the form as part of the statement of identity and use a type size that is reasonably related to the size of the letters forming the other components of the statement of identity, unless an exception applies (21 CFR 101.3(c)). Also, you must use bold type for the statement of identity, using a size reasonably related to the most prominent printed matter on the PDP, and place the statement of identity in lines generally parallel to the base of the package (21 CFR 101.3(d)).

We do not consider the firm's brand name to be mandatory information or part of the statement of identity. However, if the brand name is the most prominent printed matter on the PDP (as it often is), the regulations require the statement of identity to be in a font size that is reasonably related to the brand name (because that is the most prominent printed matter on the PDP)[3].

FDA regulations at 21 CFR 102.5 contain general principles for determining an appropriate common or usual name that may be used as the statement of identity for non-standardized foods. The common or usual name of a food must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients (e.g., "milk-based" or "soy-based") (21 CFR 102.5(a)). Also, the name must be uniform among all identical or similar

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[2] The "principal display panel," for a food in package form, is defined as the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale (21 CFR 101.1).

[3] In determining reasonable sizes for labeling information, you should also keep in mind section 403(f) of the FD&C Act (21 U.S.C. 343(f)), which deems misbranded any food "[i]f any word, statement, or other information required by or under the [FD&C Act] to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name (21 CFR 102.5(a)). Therefore, a label stating "Infant Formula" may not be sufficient to appropriately describe a product when it is, for example, a "Soy-Based Infant Formula Powder." In addition, all characterizing information should be included in the statement of identity, rather than scattered in various places on the PDP. Infant formula manufacturers should make sure the statement of identity on their products adheres to the applicable regulations, particularly those identified in this guidance document.

FDA regulations at 21 CFR 107.10 contain requirements for certain nutrient information to be included in infant formula labeling. Under 21 CFR 107.10(b)(4)(i), the statement "Infant Formula With Iron," or a similar statement, is required if the product contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption. Otherwise, 21 CFR 107.10(b)(4)(ii) requires the statement "Additional Iron May Be Necessary," or a similar statement, if the product contains less than 1 milligram of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption. Whichever statement is required must appear on the PDP (21 CFR 107.10(b)(4)). Although we do not consider the statement "Additional Iron May Be Necessary" to be part of the statement of identity, when this statement is required, we encourage infant formula manufacturers to place the statement near the statement of identity.

With regard to exempt infant formula (an infant formula that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems (21 CFR 107.3)), FDA considers specific information targeting the intended population and describing the characterizing properties of the food to be information about the basic nature of the food that must be included as part of the statement of identity (21 CFR 102.5). Therefore, stating "Infant Formula" may not sufficiently describe a product when it is, for example, a "High Protein (3.5g protein per 100 calories) Milk-Based Infant Formula Powder for Premature and Low Birth Weight Infants."

III. Exempt Infant Formulas

Infant formulas have special nutritional labeling requirements at 21 CFR 107.10,[4] and infant formulas must contain certain nutrients within a specified range as given in 21 CFR 107.100. However, some deviations from these nutritional labeling requirements and nutrient specifications are permitted for "exempt" infant formulas, as discussed below.

Exempt infant formulas, in contrast to "regular" (nonexempt) infant formulas, are those which are represented or labeled for use by an infant who has an inborn error of metabolism or a low birth weight, or who otherwise has an unusual medical or dietary problem (section 412(h)(1) of the FD&C

[4] Therefore, infant formulas are not covered by the standard nutrition labeling regulations in 21 CFR 101.9 (21 CFR 101.9(j)(7)).

Act (21 U.S.C. 350a(h)(1)) and 21 CFR 107.3 and 107.50). Although these products may deviate from the nutritional labeling requirements and nutrient specifications, they must comply with 21 CFR 107.50. For example, before processing an exempt infant formula or a reformulation of an exempt infant formula, manufacturers must submit to FDA the labeling and other information as required in 21 CFR 107.50(b)(3) and (4), and 21 CFR 107.50(c)(4). Furthermore, manufacturers of exempt infant formulas may only deviate from the nutritional labeling requirements and nutrient specifications under specific, limited circumstances in which the deviation is deemed necessary and will adequately protect the public health (21 CFR 107.50(d)(4)). In assessing whether public health is adequately protected, FDA will consider, for example, whether a deviation from the nutritional requirements of section 412(g) of the FD&C Act (21 U.S.C. 350a(g)) and regulations promulgated under section 412(a)(2) of the FD&C Act (21 U.S.C. 350a(a)(2)) is necessary to provide an exempt infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition (21 CFR 107.50(d)(4)(i)). FDA will also consider whether a deviation from the labeling requirements is necessary if label information, including pictograms and symbols required by the labeling regulations, could lead to inappropriate use of the product (21 CFR 107.50(d)(4)(iii)).

IV. Nutrient Content Claims

A nutrient content claim is a claim that expressly or impliedly characterizes the level of a nutrient which is of the type required to be in nutrition labeling (see 21 CFR 101.13(b)). Under section 403(r)(2)(A)(i) of the FD&C Act (21 U.S.C. 343(r)(2)(A)(i)), a nutrient content claim may be made on the label or labeling of a food only if it is made pursuant to a regulation authorizing its use.[5] Under 21 CFR 101.13(b)(3), no nutrient content claims may be made on infant formulas unless the claim is specifically provided for under 21 CFR parts 101, 105, or 107, or unless the claim relates to vitamin or mineral content as described in 21 CFR 101.13(q)(3). Existing FDA regulations provide for the following nutrient content claims on products intended for use by infants[6]:

- A statement that describes the percentage of a vitamin or mineral in the infant formula, in relation to a Reference Daily Intake (RDI) as defined at 21 CFR 101.9, unless such claim is expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the FD&C Act (21 U.S.C. 343(r)(2)(A)(vi)) (21 CFR 101.13(q)(3)(i));
- A factual statement that a food is unsweetened or contains no added sweeteners (in the case of a food that contains apparent substantial inherent sugar content) (21 CFR 101.60(c)(3));

[5] See 21 CFR part 101, subpart D for information regarding specific requirements for nutrient content claims, including requirements for petitions for nutrient content claims.

[6] We also note that the statement "Infant Formula With Iron" or similar is required for infant formulas that contain 1 milligram or more of iron per 100 kilocalories when the product is prepared in accordance with label directions for infant consumption (21 CFR 107.10(b)(4)(i)).

- Certain sugar content claims (such as "sugar free" or "no added sugar") on dietary supplements of vitamins or minerals (21 CFR 101.60(c)(4)); and
- A factual statement that a food is unsalted, if such statement refers to the taste of the food and is not otherwise false or misleading (21 CFR 101.61(c)(3)).

Exempt infant formulas may contain nutrients for the dietary management of specific diseases, disorders, or medical conditions.[7] The labels for these products are exempt from the nutrient content claims regulations described in the paragraphs above (21 CFR 101.13(q)(4)(i)). To avoid the possibility of misleading consumers about the benefits of an exempt infant formula, you should base any claims on the formulation and intended use of the exempt infant formula product.

The following are examples of claims on exempt infant formulas that we would likely not consider to be misleading:

- A claim on an exempt infant formula for premature and low birth weight infants regarding the added amount of protein, because the higher level of protein is essential for the growth and development of this population.

- A claim on an exempt infant formula intended for infants with proven methylmalonic (MMA) or propionic (PA) acidemia regarding the level of isoleucine on the labeling, because the level of isoleucine in the product is essential information for the care provider to know prior to feeding the infant. A possible example would be a claim of "Low Isoleucine" accompanied by an asterisk to a footnote indicating the amount of isoleucine in the product.

V. Health Claims and Qualified Health Claims

A health claim is a claim that characterizes the relationship of any nutrient which is of the type required to be on the label or labeling of a food to a disease or a health-related condition (see 21 CFR 101.14(a)(1)). Health claims may be made on the label or labeling of an infant formula if the claim is allowed under 21 CFR part 101 subpart E (see 21 CFR 101.14(e)(5)) (see also section 403(r)(1)(B) of the FD&C Act (21 U.S.C. 343(r)(1)(B)). Information about how to petition FDA regarding the use of a health claim is available in 21 CFR 101.70.

[7] As discussed in section III of this guidance, certain deviations from the infant formula nutrient labeling regulations in 21 CFR 107.10 and from the nutrient specifications in 21 CFR 107.100 are permitted for exempt infant formulas (21 CFR 107.50(d)(4)(i)).

FDA has permitted the use of a qualified health claim[8] regarding the relationship between the consumption of 100% Whey-Protein Partially Hydrolyzed infant formula and a reduced risk of atopic dermatitis, if manufacturers meet the following two conditions[9]:

1. The qualified health claim is worded appropriately. The following qualified health claims are those for which we intend to consider the exercise of our enforcement discretion:

    - "Very little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age."
    - "Little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life."
    - "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is very little scientific evidence for the relationship."

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[8] A qualified health claim characterizes the relationship between a substance and a disease or health-related condition, but is a claim that has not been approved by FDA under the "Significant Scientific Agreement" standard that characterizes health claims, and thus must be accompanied by a disclaimer or otherwise qualified in such a way as to not mislead consumers. FDA considers qualified health claims under its interim procedures; we issue letters of enforcement discretion for claims made by petitioners indicating that based on the totality of the available evidence, we do not intend to object to the use of the claim as specified in the letter. See January 2013 "Guidance for Industry: A Food Labeling Guide (8. Claims)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

[9] Petition response letter, "100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis" (May 2011), available at http://wayback.archive-it.org/7993/20171114183649/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm.

- "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship."

2. The following language, including the specified use of bold font, is included with any of the qualified health claims listed above:

> "Partially hydrolyzed formulas **should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms**. If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby's care and feeding choices should be under a doctor's supervision."

VI. Additional Infant Formula Labeling Requirements

Additional infant formula labeling requirements under 21 CFR 107.20, "Directions for use," require manufacturers to bear specific label statements on all infant formula products, as detailed below.

A. Directions for Preparation and Use

Under the heading "Directions for Preparation and Use" (21 CFR 107.20(a)), the product label must bear the following directions for use:

- Storing the infant formula before and after opening the container, including a statement to avoid prolonged storage at excessive temperatures;
- Agitating liquid infant formula before opening the container, e.g., "Shake well before opening";
- Sterilizing water, bottles, and nipples when necessary before preparing infant formula for use; and
- Diluting infant formula, when appropriate. For powdered infant formulas, the directions must contain the weight and volume of powdered formula to be reconstituted.

B. Pictogram

In close proximity to the "Directions for Preparation and Use," the label must include a pictogram showing the major steps for preparing the infant formula (21 CFR 107.20(b)).

C. Use By Date

The product label also must bear a "Use by _" date, indicating the month and year. The manufacturer, packer, or distributor determines the "use by" date on the basis of tests or other information showing

that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by the label directions, will, when consumed, contain not less than the quantity of each nutrient, as set forth on the label, and otherwise be of an acceptable quality (21 CFR 107.20(c)).

D. Water Statement and Symbol

The label must include on the PDP, as appropriate, the statement "Add Water" for concentrated formulas, or "Do Not Add Water" for ready-to-feed formulas (21 CFR 107.20(d)). For concentrated formulas, the label must include a symbol showing water being added to the formula, in close proximity to the "Add Water" statement, and the symbol shall be placed on a white background encircled by a dark border (21 CFR 107.20(d)).

E. Warning Statement

Beneath or in close proximity to the "Directions for Preparation and Use," the label must include a warning statement that cautions against improper preparation or use, such as "THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE" (21 CFR 107.20(e)).

F. Physician's Recommendation

The label also must include a statement indicating that parents should consult their physicians about the use of infant formulas, such as "USE AS DIRECTED BY A PHYSICIAN" (21 CFR 107.20(f)).

Note that our regulation requires the statement to indicate that parents should consult "their physicians." We have noticed that some label statements direct parents to contact the manufacturer's "hotline" instead of their infants' physicians. We do not consider a statement advising parents to contact a hotline to satisfy the requirements of 21 CFR 107.20(f).

VII. General Labeling Requirements

A. Intervening Material

Under 21 CFR 101.2(e), all information required to be on the information panel[10] must appear in one place without intervening material. An ingredient statement (21 CFR 101.4) and the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5), for example, are required pieces of information which must be placed on the information panel or PDP (21 CFR 101.2(b)). Although 21 CFR 101.2 does not refer to the nutritional requirements in the infant formula regulations

[10] The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel, subject to certain exceptions (21 CFR 101.2(a)).

(21 CFR part 107), we do not consider this nutrient information to be intervening material, if the ingredient statement, name and place of business, and nutrient information are adjacent on the information panel.

B. Foreign Language and Religious Symbols

Under 21 CFR 101.15(c)(1), all words, statements, and other information required by or under the authority of the FD&C Act to appear on the label or labeling must be in English (an exception applies in Puerto Rico and United States territories where the predominant language is one other than English). Under 21 CFR 101.15(c)(2), if the label contains any representation in a foreign language, all words, statements, and other information required by or under the authority of the FD&C Act must be in that (those) language(s) and in English.

Some religious symbols, such as kosher symbols and halal symbols, tend to use foreign words as part of their symbols. We do not object to the use of religious symbols that contain foreign words and do not expect those foreign words to be translated into English.

C. Statements Intended for Specific Religious Needs

Some statements on infant formulas that are meant to serve specific religious needs may be confusing for the general population, e.g., "Contains No Dairy Ingredients. Manufactured on Dairy Equipment" on kosher/halal infant formulas. Manufacturers who wish to include religious statements on infant formula products should ensure that the intent of the statement is clear to consumers and not confusingly similar to information required for other purposes.

D. Allergen Statement

Section 403(w) of the FD&C Act (21 U.S.C. 343(w)) requires that major food allergens be identified on the label. Generally, major food allergens must be identified either in a statement beginning with the word "Contains" or by common or usual name of the allergen as part of the list of ingredients (section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)). Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines "major food allergen" to include nine types of foods, including milk and soybeans, and also extends the definition of "major food allergen" (subject to exceptions) to food ingredients that contain protein derived from one of the nine types of foods (including milk and soybeans).

Infant formulas, like other foods, must also declare the name of the source of the major food allergen if a food ingredient contains protein derived from one of the nine foods, unless an exception applies (see section 201(qq)(2) of the FD&C Act) (21 U.S.C. 321(qq)(2)).[11] Therefore, if your infant formula contains one of the major food allergens (e.g., milk or soybeans), then your food must identify the source of the ingredient either in the ingredient list or in a "Contains" statement. For example, if your infant formula contains enzymatically hydrolyzed whey protein isolate, then under section 403(w)(1)(A) of the FD&C Act (21 U.S.C. 343(w)(1)(A)), you must either declare the source in the ingredient statement, i.e., "enzymatically hydrolyzed whey protein isolate (milk)," or in a Contains statement, i.e., "Contains milk." Similarly, if your infant formula is a soybean-based formula or contains an ingredient with protein derived from soybeans, you must declare "soybeans" ("soy" and "soya" are reasonable synonyms) by one of the methods described above.

Document History

- September 2016 – First edition of guidance was issued.
- March 2023 – Second edition. The guidance was updated to include sesame as a major food allergen.

[11] Under section 201(qq)(2) of the FD&C Act (21 U.S.C. 321(qq)(2)), the term "major food allergen" means a food ingredient that contains protein derived from one of nine foods—milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame—but it excepts "any highly refined oil derived from [these nine foods] and any ingredient derived from such highly refined oil," and a food ingredient that is exempt pursuant to the exemption processes at section 403(w)(6) or (w)(7) of the FD&C Act (21 U.S.C. 343(w)(6) or (w)(7)).