Food and Drug Administration, HHS

§ 101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall

(i) The statement of ingredients required by §101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph, shall be submitted under part 10 of this chapter.

be considered to be a necessary part of
the statement of identity and shall be
declared in letters of a type size bear-
ing a reasonable relation to the size of
the letters forming the other compo-
nents of the statement of identity; ex-
cept that if the optional form is visible
through the container or is depicted by
an appropriate vignette, the particular
form need not be included in the state-
ment. This specification does not affect
the required declarations of identity
under definitions and standards for
foods promulgated pursuant to section
401 of the act.

(d) This statement of identity shall
be presented in bold type on the prin-
cipal display panel, shall be in a size
reasonably related to the most promi-
nent printed matter on such panel, and
shall be in lines generally parallel to
the base on which the package rests as
it is designed to be displayed.

(e) Under the provisions of section
403(c) of the Federal Food, Drug, and
Cosmetic Act, a food shall be deemed
to be misbranded if it is an imitation
of another food unless its label bears, in
type of uniform size and prominence,
the word “imitation” and, immediately
thereafter, the name of the food imi-
tated.

(1) A food shall be deemed to be an
imitation and thus subject to the re-
quirements of section 403(c) of the act
if it is a substitute for and resembles
another food but is nutritionally infe-
rior to that food.

(2) A food that is a substitute for and
resembles another food shall not be
deemed to be an imitation provided it
meets each of the following require-
ments:

(i) It is not nutritionally inferior to
the food for which it substitutes and
which it resembles.

(ii) Its label bears a common or usual
name that complies with the provisions
of §102.5 of this chapter and that is not
false or misleading, or in the absence
of an existing common or usual name,
an appropriately descriptive term that
is not false or misleading. The label
may, in addition, bear a fanciful name
which is not false or misleading.

(3) A food for which a common or
usual name is established by regulation
(e.g., in a standard of identity pursuant
to section 401 of the act, in a common
or usual name regulation pursuant to
part 102 of this chapter, or in a regula-
tion establishing a nutritional quality
guideline pursuant to part 104 of this
chapter), and which complies with all
of the applicable requirements of such
regulation(s), shall not be deemed to be
an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an
essential nutrient that is present in a
measurable amount, but does not in-
clude a reduction in the caloric or fat
content provided the food is labeled
pursuant to the provisions of §101.9,
and provided the labeling with respect
to any reduction in caloric content
complies with the provisions applicable
to caloric content in part 105 of this
chapter.

(ii) For the purpose of this section, a
measurable amount of an essential nu-
trient in a food shall be considered to
be 2 percent or more of the Daily Ref-
erence Value (DRV) of protein listed
under §101.9(c)(7)(iii) and of potassium
listed under §101.9(c)(9) per reference
amount customarily consumed and 2
percent or more of the Reference Daily
Intake (RDI) of any vitamin or mineral
listed under §101.9(c)(8)(iv) per ref-
erence amount customarily consumed,
except that selenium, molybdenum,
chromium, and chloride need not be
considered.

(iii) If the Commissioner concludes
that a food is a substitute for and re-
sembles another food but is inferior to
the food imitated for reasons other
than those set forth in this paragraph,
he may propose appropriate revisions
to this regulation or he may propose a
separate regulation governing the par-
ticular food.

(5) A label may be required to bear
the percentage(s) of a characterizing
ingredient(s) or information con-
cerning the presence or absence of an
ingredient(s) or the need to add an in-
redient(s) as part of the common or
usual name of the food pursuant to
subpart B of part 102 of this chapter.
(g) Dietary supplements shall be
identified by the term “dietary supple-
ment” as a part of the statement of
identity, except that the word “dine-
tary” may be deleted and replaced by
the name of the dietary ingredients in
the product (e.g., calcium supplement)
or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).


§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by §101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of §101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with §101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains percent or less of ..." or "Less than percent of ..." The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of §101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

(5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butteroil and anhydrous butterfat may be declared as "butterfat".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".