

Food and Drug Administration, HHS

§ 101.18

(5) The FDA Regional Food and Drug Director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the FDA Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(6) The FDA Regional Food and Drug Director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(D) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the FDA Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of the FDA for processing under the EPIA, or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the FDA Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the FDA Regional Food and Drug Director affirms the order he shall order that the relabeling, diversion, or destruction be accomplished within 10-working days from the date of the issuance of his decision. The FDA Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the FDA Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(F) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to relabel, divert, or destroy them within 10-working days, or if the demand is affirmed by the FDA Re-

gional Food and Drug Director after an appeal and the person in possession of such eggs fails to relabel, divert, or destroy them within 10-working days, the FDA district office, or, if applicable, the State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(8) Persons engaged in handling or storing packed shell eggs for retail distribution shall permit authorized representatives of FDA to make at any reasonable time such inspection of the establishment in which shell eggs are being held, including inspection and sampling of the labeling of such eggs as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(9) No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement requiring safe handling instructions on unpasteurized shell eggs that are less stringent than those required in paragraphs (h)(1) through (h)(5) of this section.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 22033, Apr. 29, 1977; 49 FR 13690, Apr. 6, 1984; 49 FR 28548, July 13, 1984; 61 FR 20100, May 3, 1996; 62 FR 2249, Jan. 15, 1997; 63 FR 8118, Feb. 18, 1998; 63 FR 37055, July 8, 1998; 63 FR 63982, Nov. 18, 1998; 66 FR 17358, Mar. 30, 2001; 65 FR 76111, Dec. 5, 2000; 72 FR 46378, Aug. 20, 2007]

§ 101.18 Misbranding of food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

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(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name composed in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

(3) A part of the name required by applicable Federal law or regulation.

(4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

Subpart B—Specific Food Labeling Requirements

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

(a)(1) The term *artificial flavor* or *artificial flavoring* means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in §§ 172.515(b) and 182.60 of this chapter except where these are derived from natural sources.

(2) The term *spice* means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to

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name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in § 182.10 and part 184 of this chapter, such as the following:

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as “spice and coloring” unless declared by their common or usual name.

(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleo-resin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

(4) The term *artificial color* or *artificial coloring* means any “color additive” as defined in § 70.3(f) of this chapter.

(5) The term *chemical preservative* means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food