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TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, MEAT AND POULTRY INSPECTION, DEPARTMENT OF AGRICULTURE

PART 317--LABELING, MARKING DEVICES, AND CONTAINERS

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Subpart A--General

Sec. 317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in Sec. 317.2 except that the following do not have to bear such a label.

(1) Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings

bear no information except company brand names, trade marks, or code numbers which do not include any information required by Sec. 317.2;

(2) Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

(3) Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

(4) Stockinettes used as ``operative devices'', such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

(5) Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are enclosed in a consumer size container that bears a label as described in Sec. 317.2;

(6) Containers of products passed for cooking or refrigeration and moved from an official establishment under Sec. 311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

Sec. 317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be 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. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in Sec. 317.7, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: Provided, however, That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this

part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word ``ingredients'' followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container

times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: Provided, however, That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the ``20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms ``meat,'' ``meat byproduct,'' ``meat food product,'' and terms common to the meat industry but not common to consumers such as ``picnic,'' ``butt,'' ``cala,'' ``square,'' ``loaf,'' ``spread,'' ``delight,'' ``roll,'' ``plate,'' ``luncheon,'' and ``daisy'' shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term ``spice'' means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term ``natural flavor,'' ``natural flavoring,'' ``flavor'' or ``flavoring'' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or 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 any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(ii) The term ``corn syrup'' may be used to designate either corn syrup or corn syrup solids.

(iii) The term ``animal and vegetable fats'' or ``vegetable and animal fats'' may be used to designate the ingredients of mixtures of such edible fats in product designated ``compound'' or ``shortening.'' ``Animal fats'' as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula

without a change being made in the ingredients statement on labeling materials: Provided, That the word ``and'' in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: Provided, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as ``Contains _____ percent of _____ ,'' ``Less than _____percent of _____ .'' The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with Sec. 318.7(c)(4) and part 319 of this subchapter, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer packaged products in cartons the ingredient statement may be placed on the front riser panel: Provided, That the words ``see ingredients'' followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as ``Prepared for * * *''. The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or

(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or

(iii) On the front riser panel of frozen food cartons, or

(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the

principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in Sec. 317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as ``jumbo quart,'' ``full gallon,'' ``giant

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quart,'' ``when packed,'' ``minimum,'' or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: Provided, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms ``net weight'' or ``net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ``net contents'' or ``content'' when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in Sec. 317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of \3/4\-pound avoirdupois weight shall be expressed as ``Net Wt. 12 oz.'' except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1\1/2\ pounds avoirdupois weight shall be expressed as ``Net Wt. 24 oz. (1 lb. 8 oz.),'' ``Net Wt. 24 oz. (1\1/2\ lb.),'' or ``Net Wt. 24 oz. (1.5 lbs.).''

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart, except that on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. Paragraph (h)(9) of this section permits certain exceptions from the provisions of this paragraph for margarine packages, random weight consumer size packages, and packages of less than \1/2\ ounce net weight. Pargraph (h)(12) of this section permits certain exceptions from the provision of this paragraph for multi-unit packages.

(6) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel

of the package and shall be uniform of all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on packages, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on packages, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenths inch in height on packages, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on packages, the principal display panel of which has an area of more than 100 but not more than 400 square inches.

(v) Not less than one-half inch in height on packages, the principal display panel of which has an area of more than 400 square inches.

(7) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). Heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ``o'' or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(8) The statement shall appear as a distinct item on the principal display panel and shall be separated by a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the

width of the letter ``N'' of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, ``jumbo quart,'' ``full gallon,'' ``giant quart,'' ``when packed,'' ``Minimum'' or words of similar import.

(9) The following exemptions from the requirements contained in this paragraph (h) are hereby established:

(i) Individually wrapped, random weight consumer size packages shipped in bulk containers (as specified in paragraph (h)(11) of this section) and meat products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined under Sec. 317.19 need not bear a net weight statement when shipped from an official establishment, provided that a net weight shipping statement which meets the requirements of paragraph (h)(2) of this section is applied to their shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously

on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than \1/2\ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph is they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2) of this section;

(iii) Individually wrapped and labeled packages of less than \1/2\ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of paragraphs (h) (3) and (5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as ``1 pound'' or ``one pound'' in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from the requirements of paragraphs (h)(3) and (h)(5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel, and that the statement be expressed both in ounces and in pounds, if the statement appears in a conspicuous manner on the principal display panel.

(10) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(11) As used in this section, a ``random weight consumer size package'' is one which is one of a lot, shipment or delivery of packages of the same product with varying weights and with no fixed weight pattern.

(12) On a multiunit retail package, a statement of the net quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and in parentheses, the total net quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total

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quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (h)(5) of this section. For the purposes of this section, ``multiunit retail package'' means a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (h) (2), (3), (6), and (8) of this section.

(i) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix ``EST''; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as ``EST. No. on Metal Clip'' or ``Est. No. on Pan'', if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix ``EST''.

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word ``imitation'' immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word ``ingredients:'' and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or an smoke flavoring is added as an ingredient in the formula of a meat food product, as permitted in part 318 of this subchapter, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ``Artificial Smoke Flavoring Added'' or ``Smoke Flavoring Added,'' as may be applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring so added as an ingredient in the formula of the meat food product.

(4) When any other artificial flavoring is permitted under part 318 of this subchapter to be added to a product, the ingredient statement shall identify it as ``Artificial Flavoring.''

(5) When artificial coloring is added to edible fats as permitted under part 318 of this subchapter such substance shall be declared on the label in a prominent manner and contiguous to the name of the product by the words ``Artificially colored'' or ``Artificial coloring added'' or ``With added artificial coloring.'' When natural coloring such as annatto is added to edible fats as permitted under part 318 of this subchapter, such substance shall be declared on the label in the same manner by a phrase such as ``Colored with annatto.''

(6) When product is placed in a casing to which artificial coloring is applied as permitted under part 318 of this subchapter, there shall appear on the

label, in a prominent manner and contiguous to the name of the product, the words, ``Artificially colored.''

(7) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, there shall appear on the label, in a prominent manner and contiguous to the name of product, the words ``Artificially colored.''

(8) When a casing is colored prior to its use as a covering for product and the color is not transferred to the product enclosed in the casing, no reference to color need appear on the label but no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product, or otherwise.

(9) Product which bears or contains any other artificial coloring, as permitted under part 318 of this subchapter, shall bear a label stating that fact on the immediate container or if there is none, on the product.

(10) When an antioxidant is added to product as permitted under part 318 of this subchapter, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement identifying the officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added, such as, ``BHA, BHT, and Propylgallate added to help protect flavor.''

(11) Containers of meat packed in borax or other preservative for export to a foreign country which permits the use of such preservative shall, at the time of packing, be marked ``for export,'' followed on the next line by the words ``packed in preservative,'' or such equivalent statement as may be approved for this purpose by the Administrator and directly beneath this there shall appear the word ``establishment'' or abbreviation thereof, followed by the number of the establishment at which the product is packed. The complete statement shall be applied in a conspicuous location and in letters not less than 1 inch in height.

(12) Containers of other product packed in, bearing, or containing any chemical preservative shall bear a label stating that fact.

(13)(i) On the label of any ``Mechanically Separated (Species)'' described in Sec. 319.5(a) of this subchapter, the name of such product shall be followed immediately by the phrase ``for processing'' unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any ``Mechanically Separated (Species)'' described in Sec. 319.5 of this subchapter is used as an ingredient in the preparation of a meat food product and such ``Mechanically Separated (Species)'' contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7) (i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: ``A ------ serving contains ----% of the U.S. RDA of calcium'', with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: Provided, That, calcium content need not be stated where (a) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned

ingredients or (b) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

(k) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: ``Keep Refrigerated,'' ``Keep Frozen,'' ``Perishable Keep Under Refrigeration,'' or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed

prior to or during display for sale at retail shall bear the statement on the shipping container: ``Keep Frozen.'' The consumer-size containers for such products shall bear the statement ``Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.'' For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, or other equine not heat processed in a manner that conforms to the time and temperature combinations in the Table for Time/Temperature Combination For Cooked Beef, Roast Beef, and Cooked Corned Beef in Sec. 318.17, or that have not undergone other further processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in Sec. 318.23; except as exempted under paragraph (l)(4) of this section.

(1)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (l) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading ``Safe Handling Instructions'' which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (l)(2) and (l)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (l) shall include the following rationale statement as part of the safe handling instructions, ``This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the

heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (l), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (l)(1) through (l)(3) of this section.

(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

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(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[35 FR 15580, Oct. 3, 1970]

Editorial Note: For Federal Register citations affecting Sec. 317.2,

see the List of Sections Affected in the Finding Aids section of this volume.

Sec. 317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.

(a) The Administrator may approve and authorize the use of abbreviations of marks of inspection under the regulations in this subchapter. Such abbreviations shall have the same force and effect as the respective marks for which they are authorized abbreviations.

(b) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph apply only to labels, or other marking devices, bearing or containing an official inspection legend shown in Sec. 312.2(b), Sec. 312.3(a) (only the legend appropriate for horse meat food products) or Sec. 312.3(b) (only the legend appropriate for other (nonhorse) equine meat food products), or any abbreviations, copy or representation thereof.

(c) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a brand or other marking device containing an official inspection legend, or simulation thereof, shown in Sec. 312.2(a), Sec. 312.3(a) (only the legend appropriate for horse carcasses and parts of horse carcasses), Sec. 312.3(b) (only the legend appropriate for other equine (nonhorse) carcasses and parts of other (nonhorse) equine carcasses) or Sec. 312.7(a).

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the brand or other marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the brands or other marking devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the

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remaining two copies shall be given to the brand or other marking device manufacturer.

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy

with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such brand or other marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

[35 FR 15580, Oct. 3, 1970, as amended at 50 FR 21422, May 24, 1985]

Sec. 317.4 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in Sec. 317.5(b). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in Sec. 317.4(d), for all products, except as provided in Sec. 317.5(b) (2)-(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in Sec. 317.4(a) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate form) for a product produced in other establishments that are owned by the corporation.

(d) ``Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in Sec. 317.2. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling.
Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in Sec. 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in Sec. 317.5(b)(7).

(f)(1) Consistent with the requirements of this section, temporary

approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

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(i) The proposed labeling would not misrepresent the product;
(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
(iii) Denial of the request would create undue economic hardship; and
(iv) An unfair competitive advantage would not result from the granting of the temporary approval.
(2) Extensions of temporary approvals may also be granted by the Food Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.
(g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

[60 FR 67454, Dec. 29, 1995]

Sec. 317.5 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in Sec. 317.2, and is not otherwise false or misleading in any particular.
(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 of this subchapter, as required in Sec. 317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in Sec. 335.12.
(b) Generically approved labeling is labeling which complies with the following:
(1) Labeling for a product which has a product standard as specified in part 319 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;
(2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;
(3) Labeling for containers of products sold under contract

specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with Sec. 316.13;

(5) Labeling for products not intended for human food, provided they comply with part 325 of this subchapter;

(6) Meat inspection legends, which comply with parts 312 and 316 of this subchapter;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g.,

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``lb.'' for ``pound,'' or ``oz.'' for ``ounce,'' or of the word ``pound'' for ``lb.'' or ``ounce'' for ``oz.'';

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words ``prepared for'' or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided the size of the net weight statement complies with Sec. 317.2;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word ``new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with Sec. 317.2(k);

(xvii) The addition of safe handling instructions as required by Sec. 317.2(l);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319 of this subchapter;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiii) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information; and

(xxiv) The addition or deletion of a direct translation of the English language into a foreign language for products marked ``for export only.''

[60 FR 67455, Dec. 29, 1995]

Sec. 317.6 Approved labels to be used only on products to which they are applicable.

Labels shall be used only on products for which they are approved, and only if they have been approved for such products in accordance with Sec. 317.3: Provided, That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of

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the operator of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and part 319 of this subchapter. The Administrator may upon the show of good cause grant individual extension of time as he deems necessary.

Sec. 317.7 Products for foreign commerce; printing labels in foreign

language permissible; other deviations.

Labels to be affixed to packages of products for foreign commerce may be printed in a foreign language and may show the statement of the quantity of contents in accordance with the usage of the country to which exported and other deviations from the form of labeling required under this part may be approved for such product by the Administrator in specific cases: Provided,

(a) That the proposed labeling accords to the specifications of the foreign purchaser,

(b) That it is not in conflict with the laws of the country to which the product is intended for export, and

(c) That the outside container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of this subchapter apply. The inspection legend and the establishment number shall in all cases appear in English but in addition, may appear literally translated in a foreign language.

Sec. 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

(a) No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading.

(b) The labels and containers of product shall comply with the following provisions, as applicable:

(1) Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word ``style,'' ``type,'' or ``brand,'' as the case may be, in the same size and style of lettering as in the geographical term, and accompanied with a prominent qualifying statement identifying the country, State, Territory, or locality in which the product is prepared, using terms appropriate to effect the qualification. When the word ``style'' or ``type'' is used, there must be a recognized style or type of product identified with and peculiar to the area represented by the geographical term and the product must possess the characteristics of such style or type, and the word ``brand'' shall not be used in such a way as to be false or misleading: Provided, That a geographical term which has come into general usage as a trade name and which has been approved by the Administrator as being a generic term may be used without the qualifications provided for in this paragraph. The terms ``frankfurter,'' ``vienna,'' ``bologna,'' ``lebanon bologna,'' ``braunschweiger,'' ``thuringer,'' ``genoa,'' ``leona,'' ``berliner,'' ``holstein,'' ``goteborg,'' ``milan,'' ``polish,'' ``italian,'' and their modifications, as applied to sausages, the terms ``brunswick'' and ``irish'' as applied to stews and the term ``boston'' as applied to pork shoulder butts need not be accompanied with the word ``style,'' ``type,'' or ``brand,'' or a statement identifying the locality in which the product is prepared.

(2) Such terms as ``farm'' or ``country'' shall not be used on labels in connection with products unless such products are actually prepared on the farm or in the country: Provided, That if the product is prepared in the same way as on the farm or in the country these terms, if qualified by the word ``style'' in the same size and style of lettering, may be used: Provided further, That the term ``farm'' may be used as part of a brand designation when qualified by the word ``brand'' in the same size and style of lettering,

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and followed with a statement identifying the locality in which the product is prepared: And Provided further, That the provisions of this paragraph shall not apply to products prepared in accordance with Sec. 319.106 of this subchapter. Sausage containing cereal shall not be labeled ``farm style'' or ``country style,'' and lard not rendered in an open kettle shall not be designated as ``farm style'' or ``country style.''

(3) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not relieve any establishment from the requirement that its label shall not be misleading in any particular.

(4) The term ``spring lamb'' or ``genuine spring lamb'' is applicable only to carcasses of new-crop lambs slaughtered during the period beginning in March and terminating not beyond the close of the week containing the first Monday in October.

(5)(i) Coverings shall not be of such color, design, or kind as to be misleading with respect to color, quality, or kind of product to which they are applied. For example, transparent or semitransparent coverings for such articles as sliced bacon or fresh (uncooked) meat and meat food products shall not bear lines or other designs of red or other color which give a false impression of leanness of the product. Transparent or semitransparent wrappers, casings, or coverings for use in packaging cured, cured and smoked, or cured and cooked sausage products, and sliced ready-to-eat meat food products may be color tinted or bear red designs on 50 percent of such wrapper or covering: Provided, That the transparent or semitransparent portion of the principal display panel is free of color tinting and red designs: And provided further, That the principal display panel provides at least 20 percent unobstructed clear space, consolidated in one area so that the true nature and color of the product is visible to the consumer.

(ii) Packages for sliced bacon that have a transparent opening shall be designed to expose, for viewing, the cut surface of a representative slice. Packages for sliced bacon which meet the following specifications will be accepted as meeting the requirements of this subparagraph provided the enclosed bacon is positioned so that the cut surface of the representative slice can be visually examined:

(a) For shingle-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension) of the representative slice, and this window shall be at least 1\1/2\ inches wide. The transparent window shall be located not more than five-eighths inch from the top or bottom edge of a 1-pound or smaller package and not more than three-fourths inch from either the top or bottom edge of a package larger than 1 pound.

(b) For stack-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension)

of the representative slice and be at least 1\1/2\ inches wide.

(6) The word ``fresh'' shall not be used on labels to designate product which contains any sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or which has been salted for preservation.

(7)(i) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be. An ingredient that is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as ``spice and coloring'', or ``flavoring and coloring'', as the case may be, unless such ingredient is designated by its common or usual name.

(ii) Any ingredient not designated in Sec. 317.2(f)(1)(i) of this part whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock and poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(8) As used on labels of product, the term ``gelatin'' shall mean (i) the jelly prepared in official establishments by cooking pork skins, tendons, or connective tissue from inspected and passed product, and (ii) dry commercial

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gelatin or the jelly resulting from its use.

(9) Product (other than canned product) labeled with the term ``loaf'' as part of its name:

(i) If distributed from the official establishment in consumer size containers may be in any shape;

(ii) If distributed in a container of a size larger than that sold intact at retail the product shall be prepared in rectangular form, or as in paragraph (b)(9)(iii) of this section;

(iii) If labeled as an ``Old Fashioned Loaf'' shall be prepared in a traditional form, such as rectangular with rounded top or circular with flat bottom and rounded top.

(10) The term ``baked'' shall apply only to product which has been cooked by the direct action of dry heat and for a sufficient time to permit the product to assume the characteristics of a baked article, such as the formation of a brown crust on the surface, rendering out of surface fat, and the caramelization of the sugar if applied. Baked loaves shall be heated to a temperature of at least 160 deg.F. and baked pork cuts shall be heated to an internal temperature of at least 170 deg.F.

(11) When products such as loaves are browned by dipping in hot edible oil or by a flame, the label shall state such fact, e.g., by the words ``Browned in Hot Cottonseed Oil'' or ``Browned by a Flame,'' as the case may be, appearing as part of the product name.

(12) The term ``meat'' and the names of particular kinds of meat, such as beef, veal, mutton, lamb, and pork, shall not be used in such manner as to be false or misleading.

(13) The word ``ham,'' without any prefix indicating the species of animal from which derived, shall be used in labeling only in connection with the hind legs of swine. Ham shanks as such or ham shank meat as such or the trimmings accruing in the trimming and shaping of hams shall not be labeled ``ham'' or ``ham meat'' without qualification. When used in connection with a chopped product the term ``ham'' or ``ham meat''

shall not include the skin.

(14) The terms ``shankless'' and ``hockless'' shall apply only to hams and pork shoulders from which the shank or hock has been completely removed, thus eliminating the entire tibia and fibula, or radius and ulna, respectively, together with the overlying muscle, skin, and other tissue.

(15) Such terms as ``meat extract'' or ``extract of beef'' without qualification shall not be used on labels in connection with products prepared from organs or other parts of the carcass, other than fresh meat. Extracts prepared from any parts of the carcass other than fresh meat may be properly labeled as extracts with the true name of the parts from which prepared. In the case of extract in fluid form, the word ``fluid'' shall also appear on the label, as, for example, ``fluid extract of beef.''

(16) [Reserved]

(17) When any product is enclosed in a container along with a packing substance such as brine, vinegar, or agar jelly, a declaration of the packing substance shall be printed prominently on the label as part of the name of the product, as for example, ``frankfurts packed in brine,'' ``lamb tongue packed in vinegar,'' or ``beef tongue packed in agar jelly,'' as the case may be. The packing substance shall not be used in such a manner as will result in the container being so filled as to be misleading.

(18) ``Leaf lard'' is lard prepared from fresh leaf fat.

(19) When lard or hardened lard is mixed with rendered pork fat or hardened rendered pork fat, the mixture shall be designated as ``rendered pork fat'' or ``hardened rendered pork fat,'' as the case may be.

(20) Oil, stearin, or stock obtained from beef or mutton fats rendered at a temperature above 170 deg.F. shall not be designated as ``oleo oil,'' ``oleo stearin,'' or ``oleo stock,'' respectively.

(21) When not more than 20 percent of beef fat, mutton fat, oleo stearin, vegetable stearin, or hardened vegetable fat is mixed with lard or with rendered pork fat, there shall appear on the label, contiguous to and in the same size and style of lettering as the name of the product, the words ``beef fat added,'' ``mutton fat added,'' ``oleo stearin added,'' ``vegetable stearin added,'' or ``hardened vegetable fat added,'' as the case may be. If more than 20 percent is added, the product name shall

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refer to the particular animal fat or fats used, such as, ``Lard and Beef Fat.'' The designation ``vegetable fat'' is applicable to vegetable oil, vegetable stearin, or a combination of such oil and stearin, whereas the designations ``vegetable oil'' and ``vegetable stearin'' shall be applicable only to the oil and the stearin respectively, when used in meat food products.

(22) Cooked, cured, or pickled pigs feet, pigs knuckles, and similar products, shall be labeled to show that the bones remain in the product, if such is the case. The designation ``semi-boneless'' shall not be used if less than 50 percent of the total weight of bones has been removed.

(23) When monoglycerides, diglycerides, and/or polyglycerol esters of fatty acids are added to rendered animal fat or a combination of such fat and vegetable fat, there shall appear on the label in a prominent manner and contiguous to the name of the product a statement such as

``With Monoglycerides and Diglycerides Added,'' or ``With Diglycerides and Monoglycerides,'' or ``With Polyglycerol Esters of Fatty Acids'' as the case may be.

(24) Section 407 of the Federal Food, Drug, and Cosmetic Act contains provisions with respect to colored margarine or colored oleomargarine (21 U.S.C. 347) which are set forth herein as footnote. \1\

\1\ ``Sec. 407(a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless--

(1) Such oleomargarine or margarine is packaged,

(2) The net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) There appears on the label of the package (A) The word `oleomargarine' or `margarine' in type or lettering at least as large as any other type or lettering on such label, and (B) A full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

(4) Each part of the contents of the package is contained in a wrapper which bears the word `oleomargarine' or `margarine' in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this Act (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six tenths degrees of yellow or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent'' (21 U.S.C. 347).

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(25) When approved proteolytic enzymes as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts, there shall appear on the label, in a prominent manner, contiguous to the product

name, the statement, ``Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement.

When approved inorganic chlorides as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts there shall appear on the label in a prominent manner, contiguous to the product name, the statement, ``Tenderized with (names of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be in the

solution shall also be included in the statement.

(26) When dimethylpolysiloxan is added as an antifoaming agent to rendered fats, its presence shall be declared on the label contiguous to the name of the product. Such declaration shall read ``Dimethylpolysiloxan Added.''

(27) When pizzas are formulated with crust containing calcium propionate or sodium propionate, there shall appear on the label contiguous to the name of the product the statement ``-------- added to retard spoilage of crust'' preceded by the name of the preservative.

(28) Sausage of the dry varieties treated with potassium sorbate or propylparaben (propyl p-hydroxybenzoate) as permitted by part 318 of this subchapter, shall be marked or labeled with a statement disclosing such treatment and the purpose thereof, such as ``dipped in a potassium sorbate solution to retard mold growth.''

(29) Meat of goats shall be identified as goat meat or chevon.

(30) The term ``Chitterlings'' shall apply to the large intestines of swine, or young bovine animals when preceded with the word ``Calf'' or ``Veal.'' Meat food products that contain chitterlings or calf or veal chitterlings, in accordance with Sec. 318.6(b)(8) of this subchapter shall be identified with product names that refer to such ingredients, as for instance, ``Chitterling Loaf,'' ``Chitterling Pie,'' or ``Calf Chitterlings and Gravy,'' and shall be packed in containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact and bearing such other information as is required by this part.

(31) Products that contain blood from livestock as permitted by part 318 of this subchapter shall be labeled with a name that includes the term ``blood,'' and the specific kind of blood shall be declared in the ingredient statement, e.g., ``Swine blood,'' in the manner required by this part.

(32) A calendar date may be shown on labeling when declared in accordance with the provisions of this subparagraph:

(i) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(ii) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date, in terms of ``packing'' date, ``sell by'' date, or ``use before'' date, with or without a further qualifying phrase, e.g., ``For Maximum Freshness'' or ``For Best Quality'', and such phrases shall be approved by the Administrator as

prescribed in Sec. 317.4.

(33) [Reserved]

(34) The terms ``All,'' ``Pure,'' ``100%,'' and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(35) When agar-agar is used in canned jellied meat food products, as permitted in part 318 of this subchapter, there shall appear on the label in a prominent manner, contiguous to the product name, a statement to indicate the use of agar-agar.

(36) When sodium alginate, calcium carbonate, and lactic acid and calcium carbonate (or glucono delta-lactone) are used together in a dry binding matrix in restructured, formed meat food products, as permitted in part 318 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate and lactic acid and calcium carbonate (or glucono delta-lactone).

(37) [Reserved]

[35 FR 15580, Oct. 3, 1970]

Editorial Note: For Federal Register citations affecting Sec. 317.8, see the List of CFR Sections Affected in the Finding Aids section of this volume.

Sec. 317.9 Labeling of equine products.

The immediate containers of any equine products shall be labeled to show the kinds of animals from which derived when the products are sold, transported, offered for sale or transportation or received for transportation in commerce.

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Sec. 317.10 Reuse of official inspection marks; reuse of containers bearing official marks, labels, etc.

(a) No official inspection legend or other official mark which has been previously used shall be used again for the identification of any product, except as provided for in paragraph (b) of this section.

(b) All stencils, marks, labels, or other labeling on previously used containers, whether relating to any product or otherwise, shall be removed or obliterated before such containers are used for any product, unless such labeling correctly indicates the product to be packed therein and such containers are refilled under the supervision of a Program employee.

Sec. 317.11 Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.

(a) No person shall in any official establishment apply or affix, or cause to be applied or affixed, any label to any product prepared or received in such establishment, or to any container thereof, or fill any container at such an establishment, except in compliance with the regulations in this subchapter.

(b) No covering or other container shall be filled, in whole or in

part, at any official establishment with any product unless it has been inspected and passed in compliance with the regulations in this subchapter, is not adulterated, and is strictly in accordance with the statements on the label, and such filling is done under the supervision of a Program employee.

(c) No person shall remove, or cause to be removed from an official establishment any product bearing a label unless such label is in compliance with the regulations in this subchapter, or any product not bearing a label required by such regulations.

Sec. 317.12 Relabeling products; requirements.

When it is claimed by an official establishment that any of its products which bore labels bearing official marks has been transported to a location other than an official establishment, and it is desired to relabel the product because the labels have become mutilated or otherwise damaged, a request for relabeling the product shall be sent to the Administrator, accompanied with a statement of the reasons therefor. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with labels bearing any official marks shall be done under the supervision of a Program inspector. The official establishment shall reimburse the Program, in accordance with the regulations of the Department, for any cost involved in supervising the relabeling of such product.

Sec. 317.13 Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter.

Secs. 317.14-317.15 [Reserved]

Sec. 317.16 Labeling and containers of custom prepared products.

Products that are custom prepared under Sec. 303.1(a)(2) of this subchapter must be packaged immediately after preparation and must be labeled (in lieu of information otherwise required by this part 317) with the words ``Not For Sale'' in lettering not less than three-eighth inch in height. Such exempted custom prepared products or their containers may bear additional labeling provided such labeling is not false or misleading.

[37 FR 4071, Feb. 26, 1972]

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Sec. 317.17 Interpretation and statement of labeling policy for cured

products; special labeling requirements concerning nitrate and nitrite.

(a) With respect to sections 1(n) (7), (9), and (12) of the Act and Sec. 317.2, any substance mixed with another substance to cure a product must be identified in the ingredients statement on the label of such product. For example, curing mixtures composed of such ingredients as water, salt, sugar, sodium phosphate, sodium nitrate, and sodium nitrite or other permitted substances which are added to any product, must be identified on the label of the product by listing each such ingredient in accordance with the provisions of Sec. 317.2.

(b) Any product, such as bacon and pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with Sec. 317.2(c)(1) and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term ``Uncured'' as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

(c)(1) Products described in paragraph (b) of this section or Sec. 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement ``No Nitrate or Nitrite Added.'' This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and Sec. 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement ``Not Preserved--Keep Refrigerated Below 40 deg.F. At All Times'' unless they have been thermally processed to F<INF>o 3 or more; they have been fermented or pickled to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and Sec. 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

[37 FR 16863, Aug. 22, 1972, as amended at 44 FR 48961, Aug. 21, 1979]

Sec. 317.18 Quantity of contents labeling.

Sections 317.18 through 317.22 of this part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with Sec. 317.2(h) of this part.

[55 FR 49834, Nov. 30, 1990]

Sec. 317.19 Definitions and procedures for determining net weight compliance.

(a) For the purpose of Secs. 317.18 through 317.22 of this part, the reasonable variations allowed, definitions, and procedures to be used in

determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, ``Checking the Net Contents of Packaged Goods," Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1, 3, and 4 requirements listed in paragraphs (b) and (c) of this section. Those provisions incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the Federal Register. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol

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Street NW., suite 700, Washington, DC 20408.

(b) The following NBS Handbook 133 requirements are not incorporated by reference.

Chapter 2--General Considerations

2.13.1 Polyethylene Sheeting and Film
2.13.2 Textiles
2.13.3 Mulch

Chapter 3--Methods of Test for Packages Labeled by Weight

3.11. Aerosol Packages
3.14. Glazed Raw Seafood and Fish
3.15. Canned Coffee
3.16. Borax
3.17. Flour

Chapter 4--Methods of Test for Packages Labeled by Volume

4.7. Milk
4.8. Mayonnaise and Salad Dressing
4.9. Paint, Varnish, and Lacquers--Nonaerosol
4.11. Peat Moss
4.12. Bark Mulch
4.15. Ice Cream Novelties

Chapter 5--Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting
5.5. Paper Plates
5.6. Sanitary Paper Products
5.7. Pressed and Blown Glass Tumblers and Stemware

Appendix D: Package Net Contents Regulations

D.1.1. U.S. Department of Health and Human Services, Food and Drug Administration
D.1.2. Department of Agriculture, Food Safety and Inspection Service
D.1.3. Federal Trade Commission
D.1.4. Environmental Protection Agency
D.1.5. U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms

(c) The following requirements of Supplement 1, dated September 1990, Supplement 3, dated October 1992, and Supplement 4, dated 1994, of NIST Handbook 133 are not incorporated by reference.

Supplement 1

Chapter 2 General Considerations

2.13.1. Polyethylene Sheeting and Film
2.13.2. Textiles
2.13.3. Mulch

Chapter 3 Methods of Test for Packages Labeled by Weight

3.11.4. Exhausting the Aerosol Container

Chapter 4 Methods of Test for Packages Labeled by Volume

4.6.4. Method D: Determining the Net Contents of Compressed Gas in Cylinders
4.7. Milk
4.16. Fresh Oysters Labeled by Volume

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

Supplement 3

Chapter 3 Methods of Test for Packages Labeled by Weight

3.17. Flour and Dry Pet Food

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combination of Quantities

5.4. Polyethylene Sheeting
5.5. Paper Plates
5.8. Baler Twine

Appendix A. Forms and Worksheets

Supplement 4

3.11 Aerosol Packages
3.11.1 Equipment
3.11.2 Preparation for Test

3.11.3 The Determination of Net Contents: Part 1
3.11.4 Exhausting the Aerosol Container
3.11.5 The Determination of Net Contents: Part 2

Appendix A. Report Forms

[55 FR 49834, Nov. 30, 1990, as amended at 60 FR 12884, March 9, 1995]

Sec. 317.20 Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weigh meat products sold or otherwise distributed in commerce in federally inspected meat establishments shall be installed, maintained and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology Handbook 44, ``Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices,'' 1994 Edition, October 1993, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C..

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552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) All scales used to weigh meat products sold or otherwise distributed in commerce or in States designated under section 301(c) of the Federal Meat Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh meat products unless it has been found upon test and inspection, as specified in NIST Handbook 44, to provide accurate weight. If a scale is reinspected or retested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested by a USDA official, or a State or local government weights and measures official, or State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a retain tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

[55 FR 49834, Nov. 30, 1990, as amended at 60 FR 12884, Mar. 9, 1995]

Sec. 317.21 Scales: testing of.

(a) The operator of each official establishment that weighs meat food products shall cause such scales to be tested for accuracy, in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have an FSIS approved net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with Sec. 318.4 of this subchapter.

[55 FR 49834, Nov. 30, 1990]

Sec. 317.22 Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with Sec. 317.19 shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section and be reinspected, in accordance with the requirements of this Part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

[55 FR 49834, Nov. 30, 1990]

Sec. 317.23 [Reserved]

Sec. 317.24 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive

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regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and any other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be

general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will mmnitor the use of packaging material in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information tm designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request--a minimum of 30 days--any applicable guaranty shall cease to be effective, and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishmelts packaging materials whose use cannot be confirmed as complying with FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may

render products adulterated or injurious to health.

[49 FR 2235, Jan. 19, 1984. Redesignated at 55 FR 49833, Nov. 30, 1990]