RULES AND REGULATIONS PERTAINING TO
ARKANSAS FOOD, DRUG & COSMETIC ACT

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GENERAL **Regulation 1.1** (Adopted 1-23-58)

(a) The provision of regulations promulgated under this act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in Section 2 (82-1102 Arkansas Statutes 1947) of the act shall be applicable also to such terms when used in regulations promulgated under the act.

Regulation 2.1 (Adopted 1-23-58)

Labeling includes all written, printed or graphic matter accompanying an article at any time while such article is for sale, delivery, held for sale, or offered for sale in the State of Arkansas.

Regulation 2.2 Difference of opinion among experts (Adopted 1-23-58)

The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth or a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Regulation 3.1 Guaranty (Adopted 1-23-58)

In case of the giving of a guaranty or undertaking referred to in Section 5 (b) (82-1105 (b) Arkansas Statutes 1947) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

Regulation 3.2 Advertising — Use of Colored Lights (Adopted 1-23-64)

All direct or indirect lighting for areas where foods are displayed shall be of such quality to reflect as near as possible the true color, texture and appearance of such foods as would be expected under natural daylight conditions. If fluorescent lighting is employed, the "DeLuxe Cool White" tubes shall be used. If other types of lighting is used, the use of tinted bulbs, shades, reflectors, or surroundings shall not be employed that would cause the products to appear better or of greater value than they are.

Regulation 5.1 Guaranty: Definition, and Suggested Forms (Adopted 1-23-58)

(a) A guaranty or understanding referred to in Section 5 (b) (82-1105 (b) Arkansas Statutes 1947) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) general and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under Section 5 (b) (82-1105 (b) Arkansas Statutes 1947)

(1) Limited form for use on invoice or bill of sale. (Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Arkansas Food, Drug and Cosmetic Act. (Signature and post office address of person giving the guaranty or undertaking)

(2) General and Continuing Form. The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post office address of person to whom guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded with the meaning of the Arkansas Food, Drug and Cosmetic Act. (Signature and post office address of person giving the guaranty or undertaking).

(c) The application of a guaranty or undertaking referred to in Section 5 (b) (82-1105 (b) Arkansas Statutes 1947) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the Act.

(d) A guaranty or understanding, if signed by two or more persons, shall state that such person severally guarantee the article to which it applies. (e) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Regulation 9.1

There is prescribed within the meaning of Section 9 (82-1109 Arkansas Statutes 1947) of the act the following Definitions and Standards of Identity for Foods.

Part 1 — Hamburger; Definition and Standard of Identity.

1. (a) Hamburger shall be composed of only comminuted fresh and/or frozen beef meat with or without the addition of beef fat and/or seasoning. The total fat content shall not exceed 30 percent. (Adopted 1-23-58; Amended 1-31-63, 11-4-63)

Part 2 — Liquid Coffee; Definition and Standard of Identity. (Adopted 1-23-58)

2.1 (a) Liquid coffee is a beverage made by infusion or decoction from the roasted and ground seeds or beans of coffea arabica, coffea liberica, coffea robusta, or other species of coffea with water; plus the optional ingredients specified in sub-paragraph (b) of this section.

(b) The optional ingredients permitted are as follows: (1) Salt. (NaCl, common table salt)

Part 3 — Meat and Meat Products: Definitions, Ingredients and Exceptions. Adopted 1-23-58; Amended 4-24-58, 7-26-62, 1-21-63, 11-4-63, 7-25-74.

3.1 The Definition and Standards of Identity for Meat and Meat Products shall conform to those established by the Rules and Regulations Pertaining to the Arkansas Meat and Meat Products Inspection Act with the exception of Beef Patties.

3.2 (a) Beef Patties: Beef Patties shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders and/or partially defatted beef tissue may be used without added water or with added water only in amounts such that the product's characteristics are essentially that of a meat pattie, provided that no less than 65% meat is used. The common or usual name of this product shall be "Beef Pattie" or a descriptive name as "Hamburger with Extender" provided each word is given equal prominence. Such meat products may be sold to food service retail outlets for consumption on or off the premises in the cooked state.

(b) **Cured Meat:** The product obtained by subjecting meat to a process of salt, by the employment of dry common salt or of brine with or without the use of one or more of the following: sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, sugar, dextrose, corn syrup, corn syrup solids, honey or spices.

(c) **Dry Salt Meat:** The prepared meat which has been cured by the application of dry common salt with or without the use of one or more of the following: sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, sugar, dextrose, corn syrup, corn syrup solids, honey or spices.

(d) **Smoked Meat:** The product obtained by subjecting fresh meat or cured meat to the direct action of smoke, either of burning wood or of similar burning material.

(e) **Sausage Meat:** is fresh meat or prepared meat or a mixture of the same and it is sometimes comminuted. The term "sausage meat" is some times applied to bulk sausage containing no meat by-product.

(f) **Meat Food Products:** Any articles of food or any articles that enter into the composition of food which are not prepared meats but which are derived or prepared, in whole or in part, by a process of manufacture from any portion of the carcasses of cattle, swine, sheep, or goats, if such manufactured portion be all, or a considerable and definite portion, of the article, except such articles as organotherapeutic substances, meat juice, meat extract, and the like which is solely for medicinal purposes and are advertised only to the medical profession.

(g) **Pork Sausage:** Chopped or ground fresh pork which in the aggregate for each lot contains no more than 50 percent trimmable fat; that is, fat which can be removed by thorough, practicable trimming and sorting. Pork sausage may contain one or more of the following ingredients with appropriate label declarations: herbs, spices, salt, sugar, dextrose, corn syrup, corn syrup solids, and a maximum of 3 percent added water.

(h) Product labeled **"Chili Con Carne"** shall contain not less than 40 percent of meat computed on the weight of the fresh meat. Head meat, cheek meat and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label. The mixture may contain not more than 8 percent, individually or collectively, of cereal, vegetable starch, starchy vegetable flour, dried milk or non-fat dry milk.

(i) Product labeled **"Chili Con Carne with Beans"** shall contain not less than 25 percent of the meat computed on the weight of the fresh meat. Head meat, cheek meat, and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label.

(j) Products labeled **"Tamales"** shall be prepared with at least 25 percent meat computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales.

(k) **Liver Sausage,** liver loaf, liver cheese, liver paste and the like shall contain not less than 30 percent of liver computed on the weight of the fresh liver.

(l) The word **"fresh"** shall not be used on labels to designate products which contain sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, or any other preservative, or which has been salted for preservation.

(m) The words **"spice", spices",** and **"spiced"** without qualification shall not be used unless they refer to genuine natural spices.

(n) Product (other than canned product) labeled with the term *"loaf"* as its name or part of its name shall be prepared in loaf form with sufficient stability to withstand handling before being placed in a wrapper, casing, or the like.

(o) Under appropriate declaration as required by this regulation, **sausage of the kind not cooked** may contain not more than 3 1/2 percent, individually or collectively, of cereal, vegetable starch, starchy vegetable flour, dried skim milk, or dried milk with appropriate label declaration.

(p) **Breakfast Sausage** whether fresh, smoked, or canned shall not be made with product which in the aggregate for each lot contains more than 50 percent trimmable fat, or more than 3 percent added water.

(q) The preparation of **cooked cured products** such as ham, pork shoulders, pork shoulder picnics, pork shoulder butts, and pork loins, either by moist or dry heat shall not result in the finished cooked article weighing more than the fresh uncured product; that is, the weight of the skin, bones, fat and trimmings removed during the preparation shall not exceed the weight of the fresh uncured product.

(1) The weight of smoked meat products, such as hams, pork shoulders, pork shoulder picnics, pork shoulder butts, beef tongues, and the like, except hams, pork shoulder picnics and similar products prepared for canning shall not exceed the weight of the fresh uncured article.

(r) The word **"Ham"** without any prefix indicating the species of the animal from which derived, shall be used on labels or in connection with pork hams. Ham shanks as such or ham shank meat as such or the trimmings occurring in the trimming and shaping of hams shall not include the skin.

(s) The term *"baked"* shall apply to the product which has been cooked by the direct action of dry heat and for sufficient time to permit the product to assume the characteristics of a baked article. Baked loaves shall be heated to an internal temperature of at least 160° F. and baked pork cuts shall be heated to an internal temperature of at least 170° F.

(t) **Corn syrup solids,** corn syrup, or glucose syrup shall not be used, individually or collectively in an amount exceeding 2 percent (calculated on a dry basis) of all the ingredients used in preparing such meat food products as sausage, hamburger, meat loaf, luncheon meat, chopped ham or pressed ham.

(u) Imitations of meat or meat products other than those provided for by these regulations are prohibited.

(v) Fresh or frozen beef that has been comminuted, chopped, diced, or ground shall be identified as either hamburger or ground beef and shall meet the following standards. Hamburger or ground beef shall consist of comminuted, chopped, diced or ground fresh or frozen beef meat with or without the addition of beef fat and/or seasoning. The total fat content shall not exceed 30 percent.

(w) Meats that have been comminuted, ground, chopped, cubed or diced and shaped or molded into any form may be referred to as steaks, steakettes, hamburger steaks, chuckwagon steak, chopettes, etc., provided the name of the product is immediately followed with the method of processing, such as; ground, formed and cubed meat, naming the species of meat or meats used. The lettering of such statements shall be at least one-half as large as the lettering used in the name of the product.

(x) **Breaded Meat Products.** The amount of batter and breading used as a coating for such products as "Breaded Ham Sticks," "Breaded Beef Sticks," "Breaded Chopped Pork Steaks," "Breaded Veal Cutlet," and the like shall not exceed 30 percent of the weight of the finished breaded product. The ingredients of the batter and/or breading shall be shown in the descending order of their predominance.

3.3 (a) Except as hereafter provided, sausage shall be prepared with meat or meat and meat byproducts, seasoned with condimental proportions of condimental substances.

(b) There may be added to cooked sausages as bologna, wieners, luncheon loaves, etc., with appropriate label declaration, common salt, sugar (sucrose), refined corn sugar (dextrose), wood smoke, vinegar, flavoring, spices, sodium nitrate, sodium nitrite, potassium nitrate (Salt-Peter), and potassium nitrite.

(c) Sausages labeled all meat shall contain no meat by-products, binders or extenders.

(d) Sausages of the kind which is cooked may contain not more than 12 percent added water or moisture and no further tolerance and must be appropriately declared on the label.

(e) Sausage of the kind which is cooked may contain not more than 5 percent nonfat dry milk. All other types of binders or extenders are prohibited. Phosphates are prohibited in cooked sausages.

(f) Cooked sausage products containing more than 5 percent nonfat dry milk and more than 12 percent added moisture in the finished product shall be known as imitations and shall be so labeled. Imitation sausage products may contain in addition to nonfat dry milk any of the following, individually or collectively: Cereal, vegetable starch, starchy vegetable flour, soya flour, other binders or extenders.

(g) Non-specific loaves or loaves substantially made from meat and meat by-products but containing other principal ingredients such as pickles, pimento, honey, or other non-meat ingredients shall not be labeled meat loaf, ham loaf, or beef loaf, or other names which would indicate a predominance of meat.

(h) The use of sodium nitrite, potassium nitrite, sodium nitrate, potassium nitrate or combinations of nitrite and nitrate in cooked sausage shall not result in the presence of more than 200 parts per million of nitrite in the finished product. Supplies of nitrites and nitrates and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked on the container.

(i) No coloring matter or dyes shall be permitted to be mixed with a sausage product. Casing or other exterior coverings may be colored, dyed or stained provided the coloring, dye, or stain utilized does not penetrate the meat products more than 1/32 inch in depth, nor make the meat products appear better or of greater value than it actually is. Condiments, especially those highly colored, are not to be added beyond its usefulness as a seasoning. Paprika and other such products may be added as condiments but may not be added in such quantity as will affect the color of the product.

(j) Federally inspected products considered in conformity with cooked sausage requirements only.

3.4 (a) No product shall contain any substance which impairs its wholesomeness or which is not approved by the State Health Officer.

(b) Disodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, sodium pryophosphate, and sodium acid pryophosphate, may be added to the pumping pickle for cured hams and pork shoulder picnics, provided such use shall not result in more than 1/2 of 1 percent of added phosphate in the finished product and provided that the maximum amount of such phosphate which may be so used is as follows:

(1) Pumping pickle shall not contain more than 5 percent of such phosphate when dissolved in pumping pickle, a small quantity of a crystalline precipitate material may be formed. Such pickle shall be filtered or the precipitate allowed to settle 90 that only the clear solution is injected into the product.

(c) Ascorbic acid or sodium ascorbate may be used in the preparation of cured pork and beef products and comminuted meat food products as follows:

(1) Pickle used for pumping, curing or packing pork and beef products shall not contain more than 87 1/2 ounces of ascorbic acid or sodium ascorbate to each 100 gallons of pickle.

(2) With appropriate declarations as required under this regulation, ascorbic acid or sodium ascorbate may be used in the preparation of cooked, cured comminuted meat food products in amounts not to exceed 3/4, ounce of ascorbic acid or 7/8 ounce of sodium ascorbate for each 100 pounds fresh meat or meat food product.

(d) Harmless synthetic flavoring may be added to the products for which they are approved by the State Health Officer. The label must state that it is artificially flavored and the ingredient statement shall identify it as an artificial flavoring.

3.5 (a) All forms of fresh pork, including fresh unsmoked sausage containing pork muscle tissue and pork such as bacon and jowls other than those covered by paragraph (b) below are classed as products that are customarily well-cooked in the home or elsewhere before eaten. Therefore, the treatment of such products for the destruction of trichinae is not required.

(b) The below named products, containing pork muscle tissue (including hearts, pork stomachs and pork livers, or the pork muscle tissue which forms an ingredient of such products), shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae: bologna, frankfurters, smoked sausage, all forms of summer or dried sausage, cooked loaves, roasted, baked, boiled or cooked hams, pork shoulder picnics, or any other product falling in this category.

(c) **Heating:** All parts of the pork muscle tissues shall be heated to a temperature not lower than 137° F., and the method used shall be one known to insure such a result.

3.6 Chopped Ham: Identity; Optional Ingredients, Labeling. (a) Chopped ham is the semisolid meat product in the form of a compact mass with a limited amount of cooked-out juices, which is prepared with ham, curing agents, seasoning and any of the optional ingredients listed in paragraph (b) of this section, in accordance with the provisions:

(1) Fresh ham, cured ham, or smoked ham, or a mixture of two or more of such meat components may be used. The weight of the cured chopped ham prior to processing shall not exceed the weight of the fresh uncured ham and fresh uncured ham shank meat if any is used, exclusive of the bones and fat removed in the boning operations, plus the weight of the curing ingredients and 3 percent moisture.

(2) The curing agents which may be used, singly or in combination, are salt, sodium nitrate, sodium nitrite, potassium nitrate, and potassium nitrite. When sodium nitrate, sodium nitrite, potassium nitrate or potassium nitrite is used, singly or in combination, the amount thereof shall not exceed that permitted in this regulation.

(3) The seasonings which may be used, singly or in combination, are salt, sugar (sucrose or dextrose), spice and flavoring, including essential oils, oleoresins, and other spice extractives.

(b) Chopped ham may contain one or more of the following optional ingredients.

(1) Finely chopped ham shank meat (fresh, cured or smoked, or a combination thereof) to the extent of not more than 25 percent over that normally present in the boneless ham.

(2) Water, for the purpose of dissolving the curing agents, and not in excess of the amount permitted in paragraph (a) (1) of this section.

(3) Monosodium glutamate.

(4) Hydrolyzed plant protein.

(5) Corn syrup solids, corn syrup and glucose, singly or in combination, in an amount not to exceed 2 percent (calculated on a dry basis) of all the ingredients used in preparing the chopped ham.

(6) Disodium phosphate, sodium hexametaphosphate, sodium pryophosphate, and sodium acid pryophosphate, singly or in combination, in an amount not to exceed that permitted in this regulation.

(7) Ascorbic acid, sodium ascorbate, isoascorbic acid or sodium isoascorbate in an amount not to exceed that permitted in this regulation.

(8) Dehydrated onions or onion powder.

(9) Dehydrated garlic or garlic powder.

(c) The label shall bear the name "chopped ham."

Regulation 10 — Food, Adulteration (Adopted 10-25-62)

10.1 — Poisonous Compounds in Food Establishments.

All poisonous compounds used in the extermination of rodents or insects shall be so colored as to be easily identified. Where such poisons are used in any food-handling establishments to control rodents or insects, great care must be taken to prevent contamination of food. Poisonous compounds must not be stored directly above or near foodstuff, nor in any other manner whereby contamination of food, utensils, or equipment may occur.

10.2 — Handling of Artificially Colored Potatoes. (Adopted 4-21-53)

(1) No artificially colored potatoes shall be sold, offered for sale, or stored for sale within the State of Arkansas.

(2) These regulations shall not apply to potatoes bearing artificial color which are stored in Arkansas for the purpose of being offered for sale in States which do not prohibit or restrict the sale of colored potatoes.

(3) The application of non-toxic polishing or coating materials to potatoes when such use does not conceal damage or inferiority, is not a matter of objection, providing such polishing or coating materials do not contain coloring agents.

Regulation 11 — Food, Labeling (Adopted 1-23-58)

11.1 — Food; Labeling; Misbranding.

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

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

11.2 — Food, Labeling; Required Statements; When Exempt. (Adopted 1-23-58)

(a) Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by. . . .", "Distributed by. . . .", or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed if such statement is not misleading in any particular.

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

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure, if the food is liquid, or in terms of weight if the food is solid, semi-solid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof and except in case of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the county to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of food as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such food under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1 3/4 quarts may be expressed as "1 quart 1 1/2 pints" or "1 quart 8 fluid ounces"; 1 1/4 pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1 1/2 quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1 1/2 pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice. But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of Section 11 (e) (82-1111) of the act if:

(1) The quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of Section 11 (f) (82-1111) of the Act and Regulations promulgated thereunder.

(n) A food shall be exempt while held for sale from the requirements of clause (2) of section 11 (e) (82-1111) of the act (requiring a statement on the label of the quantity of contents) if said food, having been received in bulk containers at a retail establishment, is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

11.3 Food; Labeling; Prominence of Required Statements. (Adopted 1-23-58)

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 11 (f) (82-1111) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more park or panels of the label, each of which has sufficient space thereof, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 11 (e) or (i) (82-1111) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space, to give greater conspicuousness to any word, statement, or other information that is required by Section 11 (f) (82-1111) of the act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) 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.

(2) If the label contains any representation in a foreign language, all words, statement, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

11.4 Carbonated Beverages (Adopted 1-23-58)

(a) A carbonated beverage sold under a distinctive name, may be exempt from the provisions of section 11 (i) (2) (82-1111) of the act if the parent firm, licensee or franchise owner shall file with the Board of Health a list of ingredients used in the carbonated beverage, except that spice, flavoring, or coloring may be designated as spice, flavoring, or coloring without naming each.

11.5 Conformity to Definition and Standards of Identity (Adopted 1-23-58)

In the conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard;

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

11.6 Food; Labeling; Designation of Ingredients (Adopted 1-23-58)

(a) The name of an ingredient (except a spice, flavoring or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring) required by section 11 (i) (2) (82-1111) of the act to be borne on the label of a food shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under Section 9 (82-1109) of the act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) 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, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which 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 specific name.

(d) A label may be misleading by reason (among other reasons) if:

> (1) The order in which the names or ingredients appear thereon, or the relative prominence otherwise given such names; or
>
> (2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of clause (2) of section 11 (i) (82-1111) of the act if all words, statements, and other information required by or under authority of the act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 11 (f) (82-1111) of the act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by section 11 (e) (2), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

> (2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 11 (i) (82-1111) of the act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as practicable and which are not misleading, indicating that other ingredients may be present.

(f) A food shall be exempt while held for sale from the requirements of clause (2) of section 11 (i) (82-1111) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients) of said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to clause (2) of section 11 (i) (82-1111).

11.7 Special Dietary Use (Adopted 1-23-58)

(a) The term "special dietary uses," as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood.

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under section 11 (j) (82-1111) of the act shall be construed u exempting any food from any other provision of the act or regulation thereunder, including section 11 (a) and (g) (82-1111), and when applicable, the provisions of section 14 and 15 (82-1114 and 82-1115). DRUGS AND DEVICES REGULATION 12 SECTION 1. DEFINITIONS — PRESCRIPTION DEVICE ADOPTED (JUNE 12, 1985) A device which, because of any potentially for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate" directions for use cannot be prepared, and with the statement "Caution: federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian" printed on the label, of the device, shall be deemed a prescription device. A prescription device shall be delivered to the ultimate purchaser or user by a licensed practitioner in the course of his professional practice or upon the oral or written prescription order lawfully issued in the course of his professional practice, and dispensed by a licensed pharmacist, which the labeling of such device dispensed to contain the name and address of the dispenser, the serial number and date of dispensing, the name of the prescriber, the name of the patient, the directions for use, and containing statements, if any, contained in such prescription order.

SECTION 2. DEFINITIONS — DRUGS, DEVICES ADOPTED (June 12, 1985)

Food supplements, herbs, vitamins, minerals, or any substance, product or device, advertised or sold for use in the diagnosis, cure, mitigation, treatment or prevention of disease, as a remedy, or to affect the structure or any function of the body shall be deemed a drug or device by definition and subjects the person or persons manufacturing, distributing, possessing, holding for sale,

selling, dispensing, or giving of any such article or device to the provisions of the Arkansas Acts 1953, No. 415 and these rules and regulations.

SECTION 3. LABELING FOR SMALL PACKAGES — DRUGS ADOPTED (AUGUST 6, 1981)

A manufacturer or distributor when distributing a drug in Arkansas which is packaged in container too small to accommodate a label bearing the name and place of business of the manufacturer of the final dosage form of the drug shall place this required information on the carton, outer container, wrapper or leaflet accompanying the package upon approval of the Director of the Department of Health or his designated representative.