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**Rules of  
Department of Health  
Division 20—Division of Environmental  
Health and Epidemiology  
Chapter 2—Protection of Drugs and Cosmetics**

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## Title 19—DEPARTMENT OF HEALTH

### Division 20—Division of Environmental Health and Epidemiology Chapter 2—Protection of Drugs and Cosmetics

#### 19 CSR 20-2.010 Inspection of the Manufacture and Sale of Drugs and Devices

*PURPOSE: This rule establishes manufacturing and labeling standards for drugs and devices as related to public health protection.*

(1) A new drug may arise for the following reasons:

(A) When the use of any substance which composes a drug in whole or in part is new, whether it be an active substance or a menstrum excipient, carrier, coating or other component;

(B) When two (2) or more substances, none of which is a new drug, are combined;

(C) When the proportion of a substance in a combination is new, even though the combination containing the substance in another proportion is not a new drug;

(D) When a drug is used to diagnose, cure, treat or prevent a disease or to affect a structure or function of the body, even though the drug is already being used for another disease or to affect another structure or function of the body; or

(E) When a new drug dosage, method or duration of use for a drug is recommended or suggested on the label, even though the drug is not a new drug when used in other dosages, methods or durations of usage.

(2) Identity of Drugs.

(A) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless the drug complies in identity with the identity prescribed in an official compendium under the recognized name.

(B) The term drug defined in an official compendium means a drug having the identity prescribed in an official compendium.

(C) A statement that a drug defined in an official compendium differs in strength, quality or purity from the standard of strength, quality or purity set forth for the drug in an official compendium shall show all the respects in which the drug differs and the extent of each difference.

(3) Labeling of Drugs and Devices.

(A) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase

which reveals the connection the person has with the drug or device as "Manufactured for and packed by...", "Distributed by...", "Retailled by..." or a similar word or phrase which expresses the facts.

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

(C) When a person manufactures, packs or distributes a drug or device at a place other than his/her principal place of business, the label may state the principal place of business in lieu of the actual place where each package of the drug or device was manufactured or packed as is to be distributed, if the 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 drug or device from the requirement that its label shall not be misleading in any particular.

(E) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of the drug in the package, exclusive of wrappers and other material packed with the drug.

1. 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 and users of the drug to express quantity and which give accurate information as to the quantity. If no general usage in expressing accurate information as to the quantity of the drug exists among consumers and users, the statement of the quantity of a drug which is not in tablet, capsule, ampul or other unit form shall be in terms of weight if the drug is solid, semi-solid or viscous or in terms of measure if the drug is liquid. The statement of the quantity of a drug which is in a unit form shall be in terms of the numerical count of the units, supplemented when necessary to give accurate information as to the quantity of the drug in the package by a statement in terms, manner and form as are not misleading as to the weight or measure of the units or of the quantity of each active ingredient in each unit, which will give the information.

2. The statement of the quantity of a device shall be expressed in terms of numerical count.

(F) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one (231) cubic inches and quart, pint, fluid ounce and fluid dram subdivisions, or of the liter, milliliter or cubic centimeter and shall

express the volume at sixty-eight degrees Fahrenheit (68°F) or twenty degrees Celsius (20°C).

(G) Statements of the quantity of a drug shall contain only the fractions as are generally used in expressing the quantity of the drug. A common fraction shall be reduced to its lowest terms and a decimal fraction shall not be carried out to more than three (3) places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(H) Unless made in accordance with the provisions of subsection (4)(E) of this rule, a statement of the quantity of a drug, in the terms of weight or measure applicable to the drug shall express the number of the largest unit specified in subsection (4)(F) of this rule which is contained in the package. (For example, the statement on the label of a package which contains one (1) pint of a drug shall be "1 pint" and not "16 fluid ounces.") When a 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 subsection (4)(F) of this rule. (For example, "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 contained in the package shall not equal or exceed the number of the smaller units in the next larger unit. (For example, instead of "1 quart 16 fluid ounces" the statement shall be "1 1/2 quarts" or "1 quart 1 pint.")

(I) When there exists an established custom of stating the quantity of the contents of a drug as a fraction of a unit which is larger than the quantity contained in the package or as units smaller than the largest unit in it, the statement may be made in accordance with the custom if it is informative to the consumer.

(J) The statement of the quantity of a drug or device 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, except in the case of ampuls shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to mean the minimum quantity.

(K) In a statement that expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure after the drug 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. In the case of a liquid drug in ampuls, the variation above the stated measure shall comply with the excess volume prescribed by an official compendium for filling ampuls.

(L) When the statement does not express the minimum quantity—

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

2. Variations from the stated weight, measure or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring or counting the contents of individual packages which occur in good packing practices. Variations shall not be permitted to the extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in the package shall be permitted even though overages in other packages in the same shipment or delivery compensate for the shortage.

(M) The extent of variations from the stated quantity of the contents permissible under subsections (4)(K) and (L) of this rule shall be determined by the facts in the case of each shipment or other delivery.

(N) A drug or device shall be exempt from compliance with the requirements of section 196.100.1.(2)(b), RSMo (1986) if—

1. The statement on the label of the quantity of the contents, as expressed in terms applicable to the drug or device under the provisions of subsection (3)(E) of this rule, together with all other words, statements and information required to appear on the label of a drug or device, because of insufficient label space, cannot be so placed on the label as to comply with the requirements of section 196.100.1.(3), RSMo (1986) and rules promulgated under it; or

2. The statement on the label of the quantity of the contents of the package, as expressed in terms of numerical count in compliance with subsection (3)(E) of this rule, is less than six (6) units and the units can be easily counted without opening the package.

#### (4) Prominence and Conspicuousness of Labels.

(A) A word statement or other information appearing on the label may lack that prominence and conspicuousness required by section 196.100.1.(3), RSMo (1986) because of—

1. The failure of a 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 a word, statement or information to appear on two (2) or more parts or panels of the label each of which has sufficient space and 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 the extension, so as to provide sufficient label space for the prominent placing of the word, statement or information;

4. Insufficient label space for the prominent placing of the word, statement or information resulting from the use of label space for any word, statement, design or device which is not required to appear on the label;

5. Insufficient label space for the prominent placing of a word, statement or information resulting from the use of label space to give greater conspicuousness to any other word, statement or information or to any design or device; or

6. Smallness of style or type in which a 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 rules promulgated under section 196.100.1.(2) and (5), RSMo (1986) shall apply if the insufficiency is caused by—

1. The use of label space for any word, statement, design or device which is not required to appear on the label;

2. The use of label space to give greater conspicuousness to any word, statement or other information than is required by section 196.100.1.(3), RSMo (1986); or

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

#### (5) Language in which Labels are Written.

(A) All words, statements and other information required to appear on the label(ing) shall appear in the English language.

(B) If the label(ing) contains any information in a foreign language, all words, statements and other information required to appear on the label shall appear on the label in the foreign language.

#### (6) Labeling of Habit-Forming Drugs.

(A) The name of a substance or derivative required by or under authority of section 196.100.1.(4), RSMo (1986) to be on the label

of a drug shall be the name by which the substance is designated in subsections (6)(B)—(K) of this rule.

(B) A statement on a drug label of the name of a constituent which is a chemical derivative of a substance named in section 196.100.1.(4), RSMo (1986) shall show the substance from which the constituent is derived and that the constituent is a derivative of it.

(C) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportion of the substance or derivative contained in it shall express the weight or measure of the substance or derivative in a specified unit of weight or measure of the drug. The statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(D) The statement of the percentage of the substance or derivative contained in a drug shall express the percentage by weight; except if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at sixty-eight degrees Fahrenheit (68°F) or twenty degrees Celsius (20°C) but in that case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(E) The names and quantities or proportions of all the substances and derivatives and the statement "Warning: may be habit-forming", shall immediately precede or immediately follow without intervening written, printed or graphic matter the name by which the drug is titled in the part or panel of the label which is presented or displayed under customary conditions of purchase.

(F) A drug shall not be considered to be misbranded under section 196.100.1.(4), RSMo (1986) because of failure of its label to bear the statement "Warning: may be habit-forming" if the drug is not suitable for internal use and is distributed and sold exclusively for external use involving no possibility of habit formation.

(G) The name of an ingredient, substance, derivative or preparation required by section 196.100, RSMo (1986) to be on the label of a drug shall be the name which is listed in section 196.100.1.(5)(a)(b), RSMo (1986) or if not listed shall be a specific name and not a collective name. If an ingredient is one with a name that is recognized in an official compendium and the ingredient complies with the specifications set forth in the compendium, the ingredient may be designated on the label of the drug by the common or usual name under which the specifications are set forth.

(H) When an ingredient contains a substance in a quantity or proportion required by section 196.100.1.(5)(b), RSMo (1986) to appear on the label and the ingredient is not a derivative or preparation of a substance as

defined in paragraph (1)(B)1. of this rule, the label shall bear in conjunction with the name of the ingredient a statement of the quantity or proportion of the substance in the drug.

1. An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidn", "aminopyrine" the same as "amidopyrine". The name "alcohol" without qualification means ethyl alcohol.

2. A derivative or preparation of a substance named in section 196.100.1.(5)(b), RSMo (1986) is an article which is derived or prepared from a substance by any method, including actual or theoretical chemical action.

3. A statement on the label of a drug of the name of an ingredient in it which is a derivative or preparation of a substance named in section 196.100.1.(5)(b), RSMo (1986) shall show the substance from which the ingredient is derived or prepared and state that the ingredient is a derivative or preparation of it.

(I) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportion of a substance, derivative or preparation contained in the drug shall express the weight or measure of the substance, derivative or preparation in each unit. If the drug is not in a unit form, the statement shall express the weight or measure of a substance, derivative or preparation in a specified unit of weight or measure of the drug or the percentage of a substance, derivative or preparation in the drug. The statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(J) A statement of the percentage of alcohol shall express the percentage of absolute alcohol by volume at sixty degrees Fahrenheit (60°F) or fifteen and fifty-six hundredths degrees Celsius (15.56°C). A statement of the percentage of a substance, derivative or preparation other than alcohol shall express the percentage by weight, except when both the substance, derivative or preparation and the drug containing it are liquid and the percentage may be expressed by volume at sixty-eight degrees Fahrenheit (68°F) or twenty degrees Celsius (20°C) but in that case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(K) When a statement of the quantity or proportion of a derivative or preparation in a drug is not informative to consumers or users of the drug concerning the activity or consequences of the use of it, the quantity or proportion of the substances shall be stated on the label of the drug.

#### (7) Misbranding of Drugs and Devices.

(A) A drug or device is considered misbranded when a statement on the labeling is false or misleading with respect to another drug or device.

(B) A drug containing two (2) or more ingredients is considered misbranded when the labeling includes or suggests the name of one (1) or more but not all the ingredients even though the names of all the ingredients are stated elsewhere on the labeling.

(C) A label on a drug may be misleading for the following reasons:

1. The order in which the names of ingredients, substances, derivatives or preparations appear on it or the relative prominence otherwise given the names; or

2. Its failure to reveal the proportion of, or other fact with respect to an ingredient, substance, derivative or preparation when the proportion or other fact is material in the light of the statement that the ingredient, substance, derivative or preparation is a constituent of the drug.

#### (8) Drug Labeling Exemption.

(A) A drug shall be exempt from the requirements of section 196.100.1.(5)(b), RSMo (1986) if all words, statements and other information required to appear on the label of the drug, because of insufficient label space, cannot be so placed on the label to comply with the requirements of section 196.100.1.(3), RSMo (1986) and rules promulgated under it. The exemption shall be on the condition that if omission of the statement of the quantity of contents affords sufficient space to state legibly on it all the information required, the statement of the quantity of the contents shall be omitted as authorized in section 196.100.1.(2), RSMo (1986) and the information required by it shall be stated as prominently as practicable even though the statement is not of a conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(B) A drug shall be exempt from the requirements of section 196.100.1.(5)(b), RSMo (1986) with respect to the alkaloids atropine, hyoscyne or hyoscyamine contained in the drug, if the alkaloid is contained in it as a constituent of belladonna, hyoscyamus, scopola, stramonium or other plant material or any preparation of it, which was used as an ingredient of the drug and no practical and accurate analysis exists for the quantitative determination of each alkaloid in the ingredient. The exemption shall be on the condition that the label of a drug shall state the quantity or proportion of total alkaloids contained as constituents of the drug.

#### (9) Directions for Use of a Drug.

(A) Directions for use shall include quantity of dose. When it is deemed to be in the interest of the public health for the protection of the consumer, directions shall also include:

1. Directions for use in all conditions for which the drug or device is prescribed, recommended or suggested in its labeling or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer or other conditions for which the drug or device is commonly and effectively used. If no specific claims are made for a drug which would require complete directions with limitations for use under certain conditions, etc., a label covering the commonly accepted usage will be acceptable. Directions for use should be sufficiently adequate in all cases so as to reduce the necessity for special warning statements;

2. Quantity of dose, including quantities for persons of different ages and different physical conditions;

3. Frequency and duration of administration or application;

4. Time of administration or application in relation to time of meals, time of onset of symptoms or other time factor;

5. Route or method of administration or application; or

6. Preparation for use such as shaking, dilution, adjustment of temperature or other manipulation or process.

(B) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of section 196.100, RSMo (1986)—

1. If the label of a drug or device bears the statement "Caution: to be used only by or on the prescription of...", ("physician", "dentist" or "veterinarian") and provided further that a drug or device is not a drug or device which is commonly sold or intended by the producer to be sold retail direct to the consumer and provided, further, that the drug or device is not sold except on the prescription of a physician, dentist or veterinarian; and

2. If the label of a drug or device bears the statement "To be used only for manufacturing or compounding drugs or by or on the prescription of a physician, dentist or veterinarian, if sold as a drug". Chemicals which are used both as drugs and for technical purposes are exempt from the drug labeling provisions if sold for technical purposes only when the chemicals are labeled "For technical use and not for medicinal use".

(10) When an application for the sale of a new drug is incomplete in that it does not contain all the matter required by section 196.105.1.(1) and (2), RSMo (1986) it shall not be accepted for filing; the Missouri Department of Health



shall notify the applicant of the nonacceptance and shall specify the part of the statute with which the incomplete application fails to comply. Otherwise the date on which an application is received by the division shall be considered to be the date on which the application is filed and the division shall notify the applicant of the date. If the applicant withdraws his/her application, the application shall be considered as not having been filed.

(11) A shipment or other delivery of a new drug shall be exempt from the provisions of section 196.105.1., RSMo (1986), if—

(A) A shipment or delivery is made only to and solely for investigational use by an expert qualified by scientific training and experience to investigate the safety of drugs; and

(B) The person who introduced the shipment or delivery into commerce holds a signed statement from an expert to the effect that s/he has adequate facilities for the investigation to be conducted by him/her and that the drug will be used solely by him/her or under his/her direction for the investigation, unless and until an application under section 196.105.1.(1), RSMo (1986) becomes effective with respect to the drug.

*Auth: section 196.045, RSMo (1986). This rule previously filed as 13 CSR 50-71.010. Original rule filed Nov. 17, 1949, effective Nov. 27, 1949.*

**19 CSR 20-2.020 Inspection of the Manufacture and Sale of Cosmetics**

*PURPOSE: This rule establishes manufacturing and labeling standards for cosmetics as these products relate to public health.*

(1) Labeling of a Cosmetic.

(A) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection the person has with the cosmetic. For example, "Manufactured for and packed by....", "Distributed by...." or similar phrases which expressed the facts.

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

(C) When a person manufactures, packs or distributes a cosmetic at a place other than his/her principal place of business, the label may state the principal place of business in lieu of the actual place where each package of the cosmetic was manufactured or packed

or is to be distributed, if the statement is not misleading in any particular.

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

(E) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with the cosmetic.

(F) The statement shall be expressed in 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 the cosmetic and which gives accurate information as to the quantity. If no general consumer usage in expressing accurate information as to the quantity of the cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid; or in terms of weight if the cosmetic is solid, semi-solid or viscous; or in terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(G) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one (231) cubic inches and quart, pint and fluid ounce subdivisions and shall express the volume at sixty-eight degrees Fahrenheit (68°F) or twenty degrees Celcius (20°C). In an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which the shipment is exported.

1. A statement of weight or measure in the terms specified in subsection (1)(G) of this rule may be supplemented by a statement in terms of the metric system of weight or measure.

2. Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by a statement of weight, measure or size of the individual units of the cosmetic as will give the information.

(H) Statements shall contain only fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two (2) places.

(I) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in subsection (1)(G) of this rule and which is applicable to the cosmetic under the provisions of subsections (1)(E) of this rule, the statement shall

express the number of the largest of the units contained in the package. For example, the statement on the label of a package which contains one (1) pint of cosmetic shall be "1 pint" and not "16 fluid ounces".

1. If the 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 subsection (1)(G) of this rule. For example, one and three-fourths (1 3/4) quarts may be expressed as "1 quart 1 1/2 pints" or "1 quart 1 pint 8 fluid ounces"; one and one-fourth (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 of weight or measure of the package shall not equal or exceed the number of the smaller units in the next larger weight or measure unit. 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. When there is an established custom of stating the quantity of the contents of a cosmetic as a fraction of a unit of weight or measure which is larger than the quantity contained in the package, or as units smaller than the largest unit contained in the package, the statement may be made in accordance with the custom if it is informative to consumers.

(J) The statement shall express the minimum quantity or the average quantity of the contents of the packages. If the statement is not qualified to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to mean the average quantity.

(K) If the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure by ordinary and customary exposure, after the cosmetic is received from commerce or 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.

(L) If the statement does not express the minimum quantity after the cosmetic is received from commerce or introduced into commerce—

1. Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure; or

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 to the extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic 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 the shortage.

(M) The extent of variations from the stated quantity of the contents permissible under subsections (1)(K) and (L) of this rule in the case of each shipment or other delivery shall be determined by the facts in each case.

(N) A cosmetic shall be exempt from compliance with the requirements of section 196.115, RSMo (1986) if the quantity of the contents of the package, as expressed in terms applicable to the cosmetic under the provisions of subsection (1)(E) of this rule is less than one-fourth (1/4) ounce avoirdupois or less than one-eighth (1/8) fluid ounce or less than six (6) units in case the units of the cosmetic can be easily counted without opening the package.

#### (2) Prominence and Conspicuousness of Labels.

(A) A word, statement or other information required to appear on the label may lack that prominence and conspicuousness required by section 196.115, RSMo (1986) because of—

1. The failure of a 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 a word, statement or information to appear on two (2) or more parts or panels of the label, each of which has sufficient space and 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 the extension, so as to provide sufficient label space for the prominent placing of the word, statement or information;

4. Insufficient label space for the prominent placing of the word, statement or information resulting from the use of label space for any word, statement, design or device which is not required to appear on the label;

5. Insufficient label space for the prominent placing of a word, statement or information resulting from the use of label space to give greater conspicuousness to any other word, statement or information or to any design or device; or

6. Smallness or style of type in which a word, statement or information appears; insufficient background contrast; obscuring

designs or vignettes; or crowding with other written, printed or graphic matter.

#### (3) Language in which Labels are Written.

(A) All words, statements and other information required to appear on the label(ing) shall appear in the English language.

(B) If the label(ing) contains any representation in a foreign language, all words, statements and other information required to appear on the label shall appear in the foreign language.

(4) The term coal-tar hair dyes includes all articles containing any coal-tar color or intermediate which alters the color of the hair when applied to the hair under the conditions of use prescribed on the label or under customary or usual conditions of use.

#### (5) Misleading Labeling of Cosmetics.

(A) A false or misleading representation with respect to another cosmetic renders a cosmetic misbranded.

(B) Labeling of a cosmetic which contains two (2) or more ingredients may be misleading when the cosmetic is designated on the label by a name which includes or suggests the name of one (1) or more but not all of the ingredients even though the names of all the ingredients are stated elsewhere on the label.

*Auth: section 196.045, RSMo (1986). This rule previously filed as 13 CSR 50 72.010. Original rule entitled Missouri Division of Health E 1.20 was filed on Nov. 17, 1949, effective Nov. 27, 1949.*

### 19 CSR 20-2.030 The Return and Resale of Drugs and Medicines

*PURPOSE: This rule establishes conditions for the return of drugs and medicines to the location where purchased which will provide for the necessary public health protection.*

(1) No person shall return drugs or medicines to any drug store, pharmacy or other retail or wholesale outlet or shall offer for resale any drug or medicine which has been removed from the point of original purchase and in any manner subjected to conditions which might cause contamination, deterioration or in any way affect the intended therapeutic value of the drug or medicine, except when a physician, licensed to practice in the state of Missouri may cause any of these items to be returned and resold by supplying the purchaser with an affidavit of purity and quality prepared on his/her letterhead or prescription blank and signed by him/her and covering only those

drugs or medicines originally purchased on his/her order. The existence of an affidavit of purity and quality signed by a licensed physician need not bind any pharmacist, wholesaler or retailer of drugs or medicines to accept returned goods if s/he has reason to suspect contamination, deterioration or affected therapeutic value of the article in question.

*Auth: sections 192.020 and 196.045, RSMo (1986). This rule previously filed as 13 CSR 50-73.010. Original rule filed Nov. 21, 1958, effective Jan. 20, 1959.*