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**Rules of**  
**Department of Health and**  
**Senior Services**  
**Division 20—Division of Environmental**  
**Health and Communicable Disease Prevention**  
**Chapter 2—Protection of Drugs and Cosmetics**

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**Title 19—DEPARTMENT OF  
HEALTH AND SENIOR SERVICES  
Division 20—Division of Environmental  
Health and Communicable  
Disease Prevention  
Chapter 2—Protection of Drugs  
and Cosmetics**

**19 CSR 20-2.010 Inspection of the Manu-  
facture and Sale of Drugs and Devices**  
(Rescinded October 30, 2005)

*AUTHORITY: 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. Rescinded: Filed April 15, 2005, effective Oct. 30, 2005.*

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

*PURPOSE: This rule establishes manufactur-  
ing 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 Celsius (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.

*AUTHORITY: 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.*

*\*Original authority: 196.045, RSMo 1943.*

**19 CSR 20-2.030 The Return and Resale of Drugs and Medicines**  
(Rescinded October 30, 2005)

*AUTHORITY: 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. Rescinded: Filed April 15, 2005, effective Oct. 30, 2005.*