

**§ 701.2 Form of stating labeling requirements.**

(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 602(c) 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 parts or panels of the label, each of which has sufficient space therefor, 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;

(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)(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: *Provided, however*, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other

than English, the predominant language may be substituted for English.

(2) If the label 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 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.

**§ 701.3 Designation of ingredients.**

(a) The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs unless such ingredient is identified by name. No ingredient may be designated as fragrance or flavor unless it is within the meaning of such term as commonly understood by consumers. Where one or more ingredients is accepted by the Food and Drug Administration as exempt from public disclosure pursuant to the procedure established in § 720.8(a) of this chapter, in lieu of label declaration of identity the phrase “and other ingredients” may be used at the end of the ingredient declaration.

(b) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than  $\frac{1}{16}$  of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or card. In those cases where there is insufficient space for such declaration on the package, and it is not practical to firmly affix a tag, tape, or card, the Commissioner may establish

### §701.3

### 21 CFR Ch. I (4–1–23 Edition)

by regulation an acceptable alternate, e.g., a smaller type size. A petition requesting such a regulation as an amendment to this paragraph shall be submitted pursuant to part 10 of this chapter.

(c) A cosmetic ingredient shall be identified in the declaration of ingredients by:

(1) The name specified in §701.30 as established by the Commissioner for that ingredient for the purpose of cosmetic ingredient labeling pursuant to paragraph (e) of this section;

(2) In the absence of the name specified in §701.30, the name adopted for that ingredient in the following editions and supplements of the following compendia, listed in order as the source to be utilized:

(i) CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary, Second Ed., 1977 (available from the Cosmetic, Toiletry and Fragrance Association, Inc. 1110 Vermont Ave. NW., Suite 800, Washington, DC 20005, or at the National Archives and Records Administration (NARA), which is incorporated by reference, except for the following deletions and revisions. (For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).)

(a) The following names are not adopted for the purpose of cosmetic ingredient labeling:

Acid Black 58  
Acid Black 107  
Acid Black 139  
Acid Blue 168  
Acid Blue 170  
Acid Blue 188  
Acid Blue 209  
Acid Brown 19  
Acid Brown 30  
Acid Brown 44  
Acid Brown 45  
Acid Brown 46  
Acid Brown 48  
Acid Brown 224  
Acid Orange 80  
Acid Orange 85  
Acid Orange 86  
Acid Orange 88  
Acid Orange 89  
Acid Orange 116  
Acid Red 131  
Acid Red 213

Acid Red 252  
Acid Red 259  
Acid Violet 73  
Acid Violet 76  
Acid Violet 99  
Acid Yellow 114  
Acid Yellow 127  
Direct Yellow 81  
Solvent Black 5  
Solvent Brown 43  
Solvent Yellow 63  
Solvent Yellow 90

(b) The following names are adopted for the purpose of cosmetic ingredient labeling, provided the respective monographs are revised to describe their otherwise disclosed chemical compositions, or describe their chemical compositions more precisely, and such revised monographs are published in supplements to this dictionary edition by July 18, 1980.

Acid Black 2  
Benzophenone-11  
Carbomer 934  
Carbomer 934P  
Carbomer 940  
Carbomer 941  
Carbomer 960  
Carbomer 961  
Chlorofluorocarbon 11S  
Dimethicone Copolyol  
Disperse Red 17  
Pigment Green 7  
Polyamino Sugar Condensate  
SD Alcohol (all 27 alphanumeric designations)  
Sodium Chondroitin Sulfate  
Synthetic Beeswax

(c) The following names are adopted for the purpose of cosmetic ingredient labeling until January 19, 1981.

Amphoteric (all 20 numeric designations)  
Quaternium (all 49 numeric designations)

(ii) United States Pharmacopeia, 19th Ed., 1975, and Second Supplement to the USP XIX and NF XIV, 1976. (Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).)

(iii) National Formulary, 14th Ed., 1975, and Second Supplement to the USP XIX and NF XIV, 1976. (Copies are

available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)).

(iv) Food Chemicals Codex, 2d Ed., 1972; First Supplement, 1974, and Second Supplement, 1975, which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(v) USAN and the USP dictionary of drug names, USAN 1975, 1961-1975 cumulative list. (Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)).

(3) In the absence of such a listing, the name generally recognized by consumers.

(4) In the absence of any of the above, the chemical or other technical name or description.

(d) Where a cosmetic product is also an over-the-counter drug product, the declaration shall declare the active drug ingredients as set forth in § 201.66(c)(2) and (d) of this chapter, and the declaration shall declare the cosmetic ingredients as set forth in § 201.66(c)(8) and (d) of this chapter.

(e) Interested persons may submit a petition requesting the establishment of a specific name for a cosmetic ingredient pursuant to part 10 of this chapter. The Commissioner may also propose such a name on his own initiative.

(f) As an alternative to listing all ingredients in descending order of predominance, ingredients may be grouped and the groups listed in the following manner and order:

(1) Ingredients, other than color additives, present at a concentration greater than 1 percent, in descending order of predominance; followed by

(2) Ingredients, other than color additives, present at a concentration of not more than 1 percent, without respect to order of predominance; followed by

(3) Color additives, without respect to order of predominance. Ingredients specified in paragraph (f)(2) of this section may be included with those specified in paragraph (f)(1) of this section and listed in descending order of predominance.

(g) A declaration of ingredients may include an ingredient not in the product if the ingredient is identified by the phrase "may contain" and:

(1) It is a color additive added to some batches of the product for purposes of color matching; or

(2)(i) The same declaration of ingredients is also used for other products similar in composition and intended for the same use, including products which may be assortments of products similar in composition and intended for the same use; and

(ii) Such products are "shaded" products, i.e., those falling within the product categories identified in § 720.4 (c)(3), (7) and (8)(v) of this chapter; and

(iii) All products sharing the common declaration of ingredients are sold by the labeler under a common trade name or brand designation, and no trade name or brand designation not common to all such products appears in the labeling of any of them; and

(iv) The ingredient is a color additive.

(h) As an alternative to a declaration of color additive ingredients for each product, the color additives of an assortment of cosmetic products that are sold together in the same package may be declared in a single composite list in a manner that is not misleading and that indicates that the list pertains to all the products.

### § 701.3

### 21 CFR Ch. I (4–1–23 Edition)

(i) As an alternative to the declaration of ingredients specified in paragraph (b) of this section, the declaration of ingredients may appear in letters not less than  $\frac{1}{16}$  of an inch in height in labeling accompanying the product, as for example, on padded sheets or in leaflets, if the total surface area of the package is less than 12 square inches. This paragraph is inapplicable to any packaged cosmetic product enclosed in an outer container, e.g., a folding carton. In addition, this paragraph is applicable only to cosmetic products meeting one of the following requirements:

(1) The cosmetic products are held and displayed for sale in tightly compartmented trays or racks of a display unit. The holder of the labeling bearing the declaration of ingredients shall be attached to the display unit; or

(2) The cosmetic products are “shaded” products, i.e., those falling within the product categories identified in § 720.4 (c)(3), (7) and (8)(v) of this chapter, and are held for sale in tightly compartmented trays or racks. The holder of the labeling bearing the declaration of ingredients shall be attached to a display chart bearing samples of the product shades, which is displayed to purchasers. Such a display chart shall be of such construction and design as to permit its continuous use as a display, such as on a counter, and shall be designed for the primary purpose of displaying samples of the shades of the products.

(j) The holder of labeling bearing a declaration of ingredients and used in accordance with paragraph (i) of this section shall be attached to the display unit or chart and shall meet one of the following conditions:

(1) The labeling is on the front of the display unit or chart and can be read in full by a purchaser facing the display unit or chart under customary conditions of retail sale; or

(2) The labeling is on the front of the display unit or chart, is partially visible, and is accompanied by a conspicuous notice on the front of the display unit or chart describing the location of such labeling in letters not less than  $\frac{3}{16}$  of an inch in height, e.g., “Ingredient lists above”, that can be read by a purchaser facing the display unit

or chart under customary conditions of retail sale, or by the notice required by provisions in paragraph (k)(3) of this section, if conspicuous at all times; or

(3) The labeling is on a side of the display unit or chart, but not on the top, back, or bottom, and is accompanied by a conspicuous notice on the front of the display unit or chart describing the location of such labeling in letters not less than  $\frac{3}{16}$  of an inch in height, e.g., “Ingredient lists located on right side of display”, that can be read by a purchaser facing the display unit or chart under customary conditions of retail sale.

(k) Any use of a display unit or chart bearing labeling under the provisions of paragraph (i) of this section shall meet the following requirements:

(1) All articles of labeling bearing ingredient declarations and used in conjunction with any one display unit or chart shall be identical and shall declare the ingredients of all products sold in conjunction with the display unit or chart for which the ingredient declaration is made pursuant to paragraph (i) of this section.

(2) Any display unit or chart intended for such use shall be shipped together with the labeling intended to be attached to it.

(3) Every display unit or chart and/or labeling system shall be designed so that the words “Federal law requires ingredient lists to be displayed here” in letters not less than  $\frac{3}{16}$  of an inch in height (i) become conspicuous when no ingredient declarations are displayed and when the last list has been taken, or (ii) are conspicuous at all times adjacent to the place where ingredient declarations are to be attached.

(4) Any labeling containing a declaration of ingredients which reflects a formulation change and not shipped accompanying a display unit or chart shall be dated. Whenever any formulation change is made, and the labeling containing the declaration of ingredients is thereby required to be used in conjunction with products of both the old and new formulations, the labeling shall declare the ingredients of both the old and new formulations separately in a way that is not misleading

and in a way that permits the purchaser to identify the ingredient declaration applicable to each package, or which clearly advises the purchaser that the formulation has been changed and that either declaration may be applicable.

(5) Sufficient copies of the declaration of ingredients shall be provided with each shipment of a cosmetic so that a purchaser may obtain a copy of the declaration with each purchase. Display units and replacement labeling for display units shall be accompanied by instructions to the retailer, which when followed will result in compliance with the requirements of this section. Copies of the declaration accompanying refills shall be attached to the specific refill items to which they pertain, or shall be packed with the specific refill items to which they pertain, in a container that does not contain other cosmetic products.

(6) The firm whose name appears on a product pursuant to § 701.12 shall promptly mail a copy of the declaration of ingredients to any person requesting it.

(7) The display unit or chart shall be designed and located such that the labeling is easily accessible to a purchaser facing the display unit or chart under customary conditions of retail sale.

(1) The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are:

(1) Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.

(2) Processing aids, which are as follows:

(i) Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.

(ii) Substances that are added to a cosmetic during processing for their

technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.

(iii) Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic.

(m) In the event that there is a current or anticipated shortage of a cosmetic ingredient, the declaration required by this section may specify alternatives to any ingredients that may be affected. An alternative ingredient shall be declared either (1) immediately following the normally used ingredient for which it substitutes, in which case it shall be identified as an alternative ingredient by the word "or" following the name of the normally used ingredient and any other alternative ingredient, or (2) following the declaration of all normally used ingredients, in which case the alternative ingredients in the group so listed shall be listed in expected descending order of predominance or in accordance with the provisions of paragraph (f) of this section and shall be identified as alternative ingredients by the phrase "may also contain". This paragraph is inapplicable to any ingredient mentioned in advertising, or in labeling other than in the declaration of ingredients required by this section.

(n) In the event that the shortage of a cosmetic ingredient necessitates a formulation change, packages bearing labels declaring the ingredients of the old formulation may be used if the revised ingredient declaration appears (1) on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package and bearing the conspicuous words "new ingredient list" in letters not less than  $\frac{1}{16}$  of an inch in height, or (2) on labeling inside an unsealed package and the package bears the conspicuous words, on a sticker or similar overlabeling, "new ingredient list inside" in letters not less than  $\frac{1}{16}$  of an inch in height.

### § 701.3

### 21 CFR Ch. I (4–1–23 Edition)

(o) The ingredients of products that are similar in composition and intended for the same use may be declared as follows:

(1) The declaration of ingredients for an assortment of such products that are sold together in the same package, e.g., eyeshadows of different colors, may declare the ingredients that are common to all the products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients and identifying the products in which they are present. The color additive ingredients of all the products in such an assortment, whether or not common to all the products, may be declared in a single composite list following the declaration of the other ingredients without identifying the products in which they are present.

(2) The ingredients of an assortment of such products that are sold together in the same package, e.g., eyeshadows of different colors, may be declared in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, if the package is designed such that it has a total surface area available to bear labeling of less than 12 square inches. For the purpose of this paragraph, surface area is not available for labeling if physical characteristics of the package surface, e.g., decorative relief, make application of a label impractical.

(3) The declaration of ingredients for such a product that is individually packaged and bears a label that is shared with other products pursuant to the provisions of paragraph (g)(2) of this section, e.g., one lipstick in a line of lipsticks, may declare the ingredients that are common to all such products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients in such products, and identifying the products in which they are

present. The color additive ingredients shall be declared in accordance with the provisions of paragraph (g) of this section.

(4) The declaration of ingredients for an assortment of such cosmetic products that bears a label that is shared with other products pursuant to the provisions of paragraph (g)(2) of this section, e.g., one of several compacts in a line of compacts, may declare the ingredients that are common to all such products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients in such products and identifying the products in which they are present. The color additive ingredients shall be declared in accordance with the provisions of paragraph (g) of this section.

(p) As an alternative to the declaration of ingredients in letters not less than  $\frac{1}{16}$  of an inch in height, letters may be not less than  $\frac{1}{32}$  of an inch in height if the package is designed such that it has a total surface area available to bear labeling of less than 12 square inches. For the purpose of this paragraph, surface area is not available for labeling if physical characteristics of the package surface, e.g., decorative relief, make application of a label impractical.

(q) The inside containers in a multiunit or multicomponent retail cosmetic package are not required to bear a declaration of ingredients when the labeling of the multiunit or multicomponent retail cosmetic package meets all the requirements of this section and the inside containers are not intended to be, and are not customarily, separated from the retail package for retail sale.

(r) In the case of cosmetics distributed to the consumers by direct mail, as an alternative to the declaration of ingredients on an information panel, the declaration of ingredients may appear in letters not less than  $\frac{1}{16}$  of an inch in height in labeling that accompanies and specifically relates to the

cosmetic(s) mailed, or in labeling furnished to each consumer for his personal use and from which he orders cosmetics through the mail, e.g., a direct mail sales catalog or brochure, provided all of the following additional requirements are met:

(1) The declarations of ingredients are conspicuous and presented in a way that permits the consumer to identify the declaration of ingredients applicable to each cosmetic.

(2) The package mailed to the consumer is accompanied by a notice located on, or affixed to, the top of the package or on top of the contents inside the package, or on the face of the package platform surrounding and holding the product(s), readily visible to the consumer on opening of the package, and provides the following information in letters not less than  $\frac{3}{16}$  of an inch in height:

(i) The location of the declarations of ingredients, e.g., in an accompanying brochure, or in a sales catalog used for ordering;

(ii) A statement that a copy of the declaration of ingredients will be mailed promptly to any person requesting it; and

(iii) The name and place of business of the mail order distributor.

(3) The mail order distributor promptly mails a copy of the declaration of ingredients to any person requesting it.

[39 FR 10056, Mar. 15, 1974, as amended at 40 FR 8922, Mar. 3, 1975; 40 FR 18426, Apr. 28, 1975; 42 FR 4718, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977; 42 FR 24255, May 31, 1977; 42 FR 46516, Sept. 16, 1977; 42 FR 61257, Dec. 2, 1977; 45 FR 3577, Jan. 18, 1980; 47 FR 9397, Mar. 5, 1982; 54 FR 24900, June 12, 1989; 64 FR 13297, Mar. 17, 1999; 69 FR 18803, Apr. 9, 2004; 81 FR 49897, July 29, 2016]

#### § 701.9 Exemptions from labeling requirements.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in

such establishment, from compliance with the labeling requirements of sections 601(a) and 602(b) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such cosmetic from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or