necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 8.313 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible fruits, or is a water infusion of the dried fruit. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this Subpart D as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 8.32.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 8.314 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible vegetables. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this Subpart D as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 8.32.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706 (b)(1), (c)(2), (d), 74 Stat. 399, 402; 21 U.S.C. 376 (b)(1), (c)(2), (d))

Dated: January 20, 1966.

J. K. KIRK,
Assistant Commissioner for Operations.

[F.R. Doc. 66-939; Filed, Jan. 26, 1966; 8:47 a.m.]

PART 8—COLOR ADDITIVES

Subpart D—Listing of Color Additives for Food Use Exempt From Certification

Subpart F—Listing of Color Additives for Drug Use Exempt From Certification

TITANIUM DIOXIDE

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c)(2), (d), 74 Stat. 399-403; 21 U.S.C. 376 (b), (c)(2), (d)), and under the authority delegated to him by the Secretary of Health, Education, and Welfare (21 CFR 2.90), the Commissioner of Food and Drugs, based on a petition filed by Markel & Hill, Counsel for the Titanium Dioxide Group, Washington, D.C., and other relevant material, finds that titanium dioxide is safe for use as a color additive in or on foods and drugs, under the conditions prescribed in this order and that certification is not necessary for the protection of the public health. *Therefore, it is ordered,* That Part 8 be amended by adding to Subpart D a new § 8.316 and by adding to Subpart F a new § 8.6005, as follows:

§ 8.316 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents listed in this Subpart D as safe and suitable in color additive mixtures for coloring foods, and the following:

Silicon dioxide, SiO_2 and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

Lead (as Pb)—not more than 10 parts per million.
Arsenic (as As)—not more than 1 part per million.
Antimony (as Sb)—not more than 2 parts per million.
Mercury (as Hg)—not more than 1 part per million.
Loss on ignition at 800° C. (after drying for 3 hours at 105° C.)—not more than 0.5 percent.
Water soluble substances—not more than 0.3 percent.
Acid soluble substances—not more than 0.5 percent.
TiO_2—not less than 99.0 percent after drying for 3 hours at 105° C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless its use is authorized by such standards.

(d) *Labeling requirements.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 8.32.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 8.6005 Titanium dioxide.

(a) *Identity and specifications.* (1) The color additive titanium dioxide shall conform in identity and specifications to the requirements of § 8.316 (a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents listed in this Subpart F as safe and suitable in color

additive mixtures for coloring drugs, and the following:

Silicon dioxide, SiO_2 and/or aluminum oxide Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions.* Titanium dioxide may be used for coloring ingested and externally applied drugs generally in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling requirements.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 8.32.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706 (b), (c) (2), (d), 74 Stat. 399–403; 21 U.S.C. 376 (b), (c) (2), (d))

Dated: January 20, 1966.

J. K. KIRK,
Assistant Commissioner for Operations.

[F.R. Doc. 66-938; Filed, Jan. 26, 1966; 8:47 a.m.]

PART 8—COLOR ADDITIVES

Subpart E—Listing of Color Additives for Drug Use Subject to Certification

D&C RED NO. 39; CONFIRMATION OF EFFECTIVE DATE; DELETION FROM PROVISIONAL LISTING

1. Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), (d), 74 Stat. 399–403; 21 U.S.C. 376 (b), (c), (d)), and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90), notice is given that no objections were filed to the order published in the FEDERAL REGISTER of December 9, 1965 (30 F.R. 15211), that listed D&C Red No. 39 as a color additive subject to certification for drug use. Accordingly, the regulation promulgated by that order will become effective February 7, 1966.

2. Effective February 7, 1966, § 8.501 *Provisional lists of color additives* is amended by deleting from paragraph (b) the item "D&C Red No. 39."

(Sec. 706 (b), (c), (d), 74 Stat. 399–403; 21 U.S.C. 376 (b), (c), (d))

Dated: January 20, 1966.

J. K. KIRK,
Assistant Commissioner for Operations.

[F.R. Doc. 66-940; Filed, Jan. 26, 1966; 8:48 a.m.]

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 31—NONALCOHOLIC BEVERAGES

Soda Water; Final Order Promulgating Definition and Standard of Identity

In the matter of establishing definitions and standards of identity for soda water and artificially sweetened soda water:

A notice of proposed rule making was published in the FEDERAL REGISTER of September 14, 1963 (28 F.R. 9988), setting forth proposed identity standards for the aforenamed foods based on a petition filed by American Bottlers of Carbonated Beverages, 1128 16th Street NW., Washington, D.C., 20006.

The proposed standard for soda water distinguished between articles designated as "cola" drinks (including so-called "pepper" drinks) and those articles not so designated. It was proposed that caffeine, limited to not over 0.02 percent, be listed as a mandatory ingredient for the "cola" drinks and as an optional ingredient for the other soda water drinks. It was also proposed that when caffeine is present in soda water drinks as an optional ingredient, the label should bear the statement "caffeine added" or "with caffeine."

A number of comments were received in response to this notice. Principally, these comments dealt with that portion of the proposal relating to caffeine in the cola-type beverages, and it was recommended that these beverages containing caffeine be required to bear a label declaration of that fact. This, however, would involve the basic question of whether caffeine should be a mandatory ingredient of the cola-type beverages since unless caffeine were an optional ingredient, section 401 of the Federal Food, Drug, and Cosmetic Act would not provide a basis for requiring the declaration of its presence.

The Commissioner of Food and Drugs elected to explore this problem most thoroughly through the collection and examination of samples of a substantial number of cola-type beverages being marketed throughout the United States. This survey disclosed that the proportion of caffeine varies widely from product to product with no sample collected during this survey disclosing more caffeine than the 0.02 percent contemplated in the published proposal.

It was apparent that a number of the cola-type beverages contained only that caffeine which was naturally introduced into the product through the kola nut extract used, whereas, others clearly disclosed the presence of added caffeine. In between was the class for which the analytical data were inconclusive as to whether or not the caffeine present was added.

The survey and other available information clearly demonstrate that the product made with kola nut extract will contain some caffeine, and the Commissioner has considered the possibility of issuing a standard that would endeavor through labeling to differentiate between those cola-type beverages containing only the caffeine introduced through the kola nut extract and those containing added caffeine. It is apparent, however, that there would be areas where analytical methodology would not provide a basis for this distinction, and, additionally, it is concluded that to require a label declaration of the caffeine added as such could mislead consumers into the false impression that a cola drink without a label declaration contained no caffeine, whereas, some would be present as a result of the use of the kola nut extract.

The Commissioner therefore concludes that there is not a sound basis for making caffeine an optional rather than a mandatory ingredient. Of course, as a mandatory ingredient a requirement for label declaration of caffeine is not authorized by section 401 of the act.

The proposed standard for soda water listed two vitamins, ascorbic acid and thiamine hydrochloride, as optional ingredients. The Food and Nutrition Board of the National Academy of Sciences has given special consideration to the desirability of adding vitamins to staple foods. A comment was filed by the Chairman reporting that the Food and Nutrition Board adopted at a meeting a position opposing the provision of the proposed standard that would permit the addition of the named vitamins to soda water.

The Commissioner of Food and Drugs has concluded that it would not be in the interest of consumers to provide for the addition of vitamin C and thiamine to soda water.

Upon consideration of the views and comments submitted, and other relevant information, it is concluded that it will promote honesty and fair dealing in the interest of consumers to establish a definition and standard of identity for soda water as hereinafter set forth. An order ruling on the proposed standard for artificially sweetened soda water will be published at a later date. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046, 1055, as amended, 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 341, 371) and under the authority delegated to the Commissioner by the Secretary of Health,

Education, and Welfare (21 CFR 2.90): *It is ordered*, That a new Part 31 be added to Chapter I of Title 21, as follows:

§ 31.1 Soda water; identity; label statement of optional ingredients.

(a) Soda water is the class of beverages made by absorbing carbon dioxide in potable water. The amount of carbon dioxide used is not less than that which will be absorbed by the beverage at a pressure of one atmosphere and at a temperature of 60° F. It may contain buffering agents as provided in paragraph (b) (5) of this section. It either contains no alcohol or only such alcohol (not in excess of 0.5 percent by weight of the finished beverage) as is contributed by the flavoring ingredient used. Soda water designated by a name, including any proprietary name provided for in paragraph (c) of this section, which includes the word "cola" or a designation as a "pepper" beverage that, for years, has become well known as being made with kola nut extract, and thus as a caffeine-containing drink, shall contain caffeine in a quantity not to exceed 0.02 percent by weight.

(b) Soda water may contain optional ingredients, but if any such ingredient is a food additive or a color additive within the meaning of section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act, it is used only in conformity with a regulation established pursuant to section 409 or 706 of the act. The optional ingredients that may be used in soda water in such proportions as are reasonably required to accomplish their intended effects are:

(1) Nutritive sweeteners consisting of the dry or liquid form of sugar, invert sugar, dextrose, corn sirup, glucose sirup, sorbitol, or any combination of two or more of these.

(2) One or more of the following flavoring ingredients may be added, in a carrier consisting of ethyl alcohol, glycerin, or propylene glycol:

(i) Natural flavoring derived from fruits, vegetables, bark, buds, roots, leaves, and similar plant materials.

(ii) Artificial flavoring.

(3) Natural and artificial color additives.

(4) One or more of the acidifying agents acetic acid, adipic acid, citric acid, fumaric acid, lactic acid, malic acid, phosphoric acid, or tartaric acid.

(5) One or more of the buffering agents consisting of the acetate, bicarbonate, carbonate, chloride, citrate, lactate, orthophosphate, or sulfate salts of calcium, magnesium, potassium, or sodium.

(6) One or more of the emulsifying, stabilizing, or viscosity-producing agents brominated vegetable oils, carob bean gum, glycerol ester of wood rosin, guar gum, gum acacia, gum tragacanth, hydroxylated lecithin, lecithin, methylcellulose, mono- and diglycerides of fat-forming fatty acids, pectin, polyglycerol esters of fatty acids, propylene glycol alginate, sodium alginate, sodium carboxymethycelluose, sodium metaphosphate (sodium hexametaphosphate).

(7) One or more of the foaming agents ammoniated glycyrrhizin, gum ghatti, licorice or glycyrrhiza, yucca (Joshustree), yucca (Mohave).

(8) Caffeine, in an amount not to exceed 0.02 percent by weight of the finished beverage.

(9) Quinine, as provided in § 121.1081 of this chapter, in an amount not to exceed 83 parts per million by weight of the finished beverage.

(10) One or more of the chemical preservatives sorbic acid, benzoic acid, BHA, BHT, calcium disodium EDTA, erythorbic acid, glucose-oxidase-catalase enzyme, methyl or propyl paraben, nordihydroguaiaretic acid, propyl gallate, potassium or sodium benzoate, potassium or sodium bisulfite, potassium or sodium metabisulfite, potassium or sodium sorbate, sorbic acid, sulfur dioxide, or tocopherols.

(c) (1) The name of the beverage for which a definition and standard of identity is established by this section, which is neither flavored nor sweetened, is soda water, club soda, or plain soda.

(2) The name of each beverage containing flavoring and sweetening ingredients as provided for in paragraph (b) of this section is "_____ soda" or "_____ soda water" or "_____ carbonated beverage," the blank being filled in with the word or words that designate the characterizing flavor of the soda water; for example, "grape soda." However, if the soda water is one generally designated by a particular common name; for example, ginger ale or root beer, that name may be used in lieu of the name prescribed in the first sentence of this subparagraph. For the purposes of this section, a proprietary name that is commonly used by the public as the designation of a particular kind of soda water may likewise be used in lieu of the name prescribed in the first sentence of this subparagraph.

(d) Soda water that contains the optional ingredient caffeine as provided for in paragraph (b) (8) of this section, artificial flavoring, artificial coloring, or any combination of these shall be labeled to show that fact by the label statement "with _____" or "_____ added," the blank being filled in with the word or words "caffeine," "artificial flavoring," "artificial coloring," or a combination of these words, as appropriate. If the soda water contains one or more of the optional ingredients set forth in paragraph (b) (10) of this section, which has or is intended to have a preservative effect in the finished beverage, it shall be labeled to show that fact by one of the following statements: "_____ added as a preservative" or "preserved with _____," the blank being filled in with the common name of the preservative ingredient. If soda water contains quinine salts, the label shall bear a prominent declaration either by use of the word "quinine" in the name of the article or by separate declaration.

(e) The label statements prescribed in paragraph (d) of this section for declaring the optional ingredients present shall appear on a labeling surface of the beverage in such a manner as to render the statement likely to be read by the ordinary individual under customary conditions of purchase or use of such beverage. These statements shall immediately and conspicuously precede or follow the name of the beverage, wherever such name is prominently displayed, without intervening, written, printed, or graphic matter; *Provided*, That, where such name is part of a trademark or brand, then other written, printed, or graphic matter: is also a part of such trademark or brand may intervene if the label statements required by this section are so placed as to be conspicuously related to the name of the beverage.

(Secs. 401, 701, 52 Stat. 1046, 1055 as amended, 70 Stat. 919; 21 U.S.C. 341, 371)

Any person who will be adversely affected by the foregoing order may at any time within 30 days following the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 948; 21 U.S.C. 341, 371)

Dated: January 21, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-941; Filed, Jan. 26, 1966; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals

Subpart D—Food Additives Permitted in Food for Human Consumption

IRON AMMONIUM CITRATE

The Commissioner of Food and Drugs, having evaluated the data submitted in a