of fat (and/or cholesterol, where appropriate)."

* * * * *

Because this amendment merely clarifies an existing regulation, the Commissioner finds that prior notice and public procedure are unnecessary and that good cause exists to make the order effective immediately. However, the Commissioner will consider any comments received by January 18, 1977, to determine whether this amendment should be modified or revoked.

Effective date. This amendment shall become effective on November 19, 1976.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)).)

Dated: November 12, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-33999 Filed 11-18-76;8:45 am]

[Docket No. 76P-0410]

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Informal Statements of General Policy or Interpretation; Nutrition Labeling of Restaurant Foods

The Food and Drug Administration (FDA) is amending its regulations by adding a new section to advise that nutrition information concerning combinations of restaurant foods, e.g., the total nutritional value of a combination of foods such as a hamburger, french fries, and a milk shake, may be included in advertising or labeling (other than labels), or both, without causing nutrition information to be required on each label, provided that appropriate nutrition information is effectively displayed to the customer both when he orders the food and when he consumes the food. This statement of policy shall be effective November 19, 1976.

The Commissioner of Food and Drugs issued a proposal on this matter in the FEDERAL REGISTER of December 5, 1974 (39 FR 42375). In response to the proposal, six communications were received; they came from industry, consumer organizations, and a consumer. The comments contained in these communications and the Commissioner's responses are as follows:

1. Two comments stated that nutrition labeling should be required on foods sold in "fast-food" restaurants because the wrappers, cartons, and cups used in these establishments are often impervious to soiling by food materials and are thus suited to bear nutrition labeling. These comments and an additional comment stated that the possibility that wrappers might become soiled by food materials and thus be less likely to be read by consumers was not a sufficient reason to exempt these foods from nutrition labeling.

The Commissioner has considered these comments and taken into account the fact that food wrappers and other packaging materials used in food service establishment operations frequently do bear printed material such as statements of identity and trademarks. He has concluded, based on the evidence currently before him, that such packaging is suitable for nutrition labeling.

The Commissioner recognizes that in some instances a food will unavoidably soil its wrapper, thus reducing the usefulness of information printed on the wrapper. However, he concludes that this does not seriously detract from the overall benefits to consumers that result from having nutrition information available on the wrappers.

However, in requesting the exemption, the petitioner pointed out the need for a method of furnishing nutrition information covering advertised "combinations" of foods. The Commissioner, therefore, concludes that existing nutrition labeling regulations do not always provide a practical method of communicating nutrition information concerning the total nutritional value of a combination of several items of food. The Commissioner concludes that such a practical method of furnishing nutrition information concerning combinations of restaurant foods is needed, and he is so providing in the statement of policy embodied in § 3.207 (21 CFR 3.207) being added below.

2. Two comments stated that nutrition labeling that is placed on counter placards or wall posters near the location in a "fast-food" restaurant where the menu is posted is not likely to be read due to the rapid service that is common in these establishments. One of these comments also said that, typically, only one member of a family stands in line to make the purchases for the entire family. Therefore, the other members of the family, who may be waiting in their automobile for the food, would not have the opportunity to study the wall poster or counter placard. These comments also stated that consumers often would not have the opportunity to study nutrition information posted in dining areas because the atmosphere of the establishment is designed to encourage consumers to eat the food and leave quickly rather than to take the time necessary to study the posted nutrition information. One comment suggested that nutrition information could be printed on leaflets or on napkins and inserted in paper bags along with the packaged food, or that nutrition information could be printed on paper bags or menus.

The Commissioner concludes that the proposal did not provide adequately for furnishing nutrition information to the many customers of food establishments where the food is taken out of the establishment before eating. Accordingly, he has determined that effective display of nutrition information both at the point of sale and at the point of consumption of the food is necessary if such display is in lieu of labeling the food wrappers or containers with nutrition labeling.

3. A comment filed by the petitioner opposed any attempt to change the proposal to require the use of leaflets to convey nutrition information about restaurant foods on the grounds that this would result in increased usage of paper and increased litter and solid-waste disposal problems. This comment also stated that the carton or sandwich box used by the petitioner is not suitable for nutrition labeling because the carton is designed to be opened by the customer and used as a plate, and the labeling on the outer surface of the carton is not visible after the carton has been opened. The comment further stated that the firm is considering the introduction nationally of an expended polystyrene package that would eliminate the present sandwich box and wrap, and that providing nutrition information panels on the proposed polystyrene container poses a variety of technical difficulties.

The Commissioner agrees that, insofar as practicable, the regulation should not necessitate increased use of paper in restaurant operations. Therefore, while the statement of policy published below is conditioned upon effective display of nutrition information to the customer both when he orders the food and when he consumes the food, the statement of policy permits restaurants to use any effective means of conveying the nutrition information. For example, nutrition information may be provided in dining areas by means such as wall placards or "table tents," or by printing the information on paper articles already in use in the restaurant operation, such as tray liners or napkins. To provide the nutrition information to "carry out" customers who will consume the food off the restaurant premises, the information could similarly be provided by printing it on paper articles already in use in the restaurant operation, e.g., paper bags or napkins in lieu of using separate information leaflets. Thus, sufficient flexibility is provided so that restaurants will not need to increase their usage of paper or to increase their amount of solid waste disposal.

4. One comment stated that it assumed that the proposed exemption would also apply to wrapped sandwiches sold in vending machines.

The Commissioner advises that the statement of policy would not be applicable to sandwiches sold from vending machines. The statement of policy is applicable only when a nutrition claim or information in advertising or labeling (other than a label) relates to a combination of restaurant foods. Nutrition labeling or articles in vending machines is a matter outside the scope of the statement of policy.

5. One comment stated that the proposal appeared to permit the presence of nutrition claims on food packages without requiring the packages to bear complete nutrition labeling.

The Commissioner advises that if a nutrition claim or nutrition information appears on the label of a food, the label must bear full nutrition labeling in compliance with § 1.17 (21 CFR 1.17). The statement of policy issued below does not apply when the label of a food bears any nutrition claim or nutrition information.

6. One comment stated that nutrition-labeling displays should only be required in areas near the point of purchase and should not be required in dining areas. It further stated that, once the consumer is in the dining area, he has already chosen the food, and that dining areas generally lack sufficient space for additional wall posters.

The Commissioner has concluded that a combination of restaurant foods that is otherwise subject to the requirements of nutrition labeling should not be exempted from providing nutrition information on the label(s) unless the information is effectively provided to the customer both when he orders the food and when he consumes the food. Even if the dining area displays are not used by the customer until after he has chosen that particular combination of foods, the information imparted by the nutritional labeling may well be useful to the customer in future food selection. Furthermore, it is not necessary to employ wall posters to convey the information in the dining area; any effective means, such as "table tents," printed napkins, or printed tray liners, may be used.

7. One comment stated that the petition submitted by McDonald's Corp. also included the proposal that "table tents" be used on tables in dining areas to convey nutrition information to customers after purchase of food. The comment stated that the use of "table tents" would enable purchasers choosing to eat on the premises to examine casually the nutrition information on nonsoiled media after purchase of the food.

The Commissioner advises that "table tents" may be employed to provide nutrition information in dining areas. Of course, some other means, e.g., printed bags, printed napkins, or leaflets, must be employed to convey the information to "carry out" customers who do not eat in the dining area where the table tents are used.

The December 5, 1974 proposal would exempt certain restaurant foods from nutrition labeling requirements by amending § 1.17. However, the Commissioner has decided, after further consideration of this matter, that the issuance of an informal statement of policy is more appropriate than adoption of an amendment to § 1.17. Therefore, the Commissioner is terminating the rulemaking proceeding begun by the publication of the 1974 proposal; a document to this effect appears in the proposed rules section of this issue of the FEDERAL REGISTER. Although the Federal Food, Drug, and Cosmetic Act obligates FDA to regulate food held for sale after shipment in interstate commerce, lack of sufficient enforcement resources has led FDA to recognize the primary jurisdiction of State and local governments over food service establishments. Accordingly, FDA has concentrated its regulatory efforts on assuring the safety and sanitation of food up to the point where it reaches such establishments.

The Commissioner does believe, however, that it is important that as much nutrition information as possible be made available to consumers who patronize food service establishments, especially because many teenagers subsist on "fast foods," and he believes that an informal statement of policy will be of use in encouraging the petitioners and others to provide nutrition labeling where it might not otherwise be provided.

A discussion of various aspects of the informal statement of policy follows:

GENERAL RULES REGARDING NUTRITION LABELING

Pursuant to § 1.17(a), whenever a nutrition claim or information is included on the label or in advertising for a food, the label of the food must, in the absence of an applicable exemption or an exempting statement of policy, bear information about the nutritional value of the food (calorie, protein, carbohydrate, fat, vitamin, and mineral content) in the standardized format established by § 1.17(c). Whenever a nutrition claim or information is included in labeling for a food, that labeling and the label of the food are required, in the absence of an applicable exemption or an exempting statement of policy, to bear the prescribed nutrition information.

APPLICATION OF THE GENERAL RULES TO COMBINATIONS OF RESTAURANT FOODS

Generally, restaurant foods are served without any labels. In such circumstances, nutrition claims or nutrition information in advertising or labeling do not require the presence of a label bearing nutrition information.

However, if a combination of restaurant foods is wrapped or packaged in a manner such that it bears any written, printed, or graphic matter, it then bears a "label" within the meaning of section 201(k) of the act (21 U.S.C. 321(k)). In the absence of an applicable exemption or an exempting statement of policy, any nutrition claim or nutrition information on the label(s) or in advertising makes the food subject to the requirement that label(s) bear complete nutrition information. Similarly, a nutrition claim or nutrition information in labeling, which is defined in section 201(m) of the act (21 U.S.C. 321(m)), requires complete nutrition information to appear on both that labeling and on the food label(s). For example, if a national restaurant chain advertises the nutritional value of a combination of foods consisting of a hamburger, french fries, and a milk shake and one or more of those foods is sold bearing a label, the label(s) must include complete nutrition information in the standardized format established by § 1.17(c) in the absence of an applicable exemption or an exempting statement of policy. Similarly, if other labeling that includes a nutrition claim or nutrition information about a combination of foods is provided by the restaurant and accompanies the foods, in the absence of an applicable exemption or an exempting statement of policy both the label(s) and that other labeling must include complete nutrition information in the standardized format.

EFFECT OF THE STATEMENT OF POLICY

The informal statement of policy published below will have the following effect: If any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more articles of restaurant food, e.g., a combination consisting of a hamburger, french fries, and milkshake, then, as an alternative to providing nutrition information about each separate food on the food label(s), the restaurant may instead provide information about the total nutritional value of the combination of foods (the combination as an entity without the nutritional value of each article being specified), provided that the statement of total nutritional value follows the format set forth in § 1.17(c) and provided that the nutrition information is effectively displayed to the consumer both when he orders the food and when he consumes the food.

Any appropriate and effective means may be employed for providing the required information, e.g., placards or wall posters displayed at the location where food is ordered, "table tents" or placards in the dining area of the restaurant, or leaflets, printed bags or printed napkins given to customers who carry food out.

The Commissioner advises that this statement of policy pertains only to furnishing nutrition information for combinations of restaurant foods. He further advises that, even for combinations of restaurant foods, no change has been made in the existing requirement of § 1.17(a) that any label must contain complete nutrition information in the format established by § 1.17(c) if any nutrition claim or nutrition information is included on the label, or that any other labeling must similarly bear complete nutrition information if any nutrition claim or nutrition information is included in that labeling.

Copies of the environmental and inflation impact assessments of the December 5, 1974 proposal are on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 403, 701(a), 52 Stat. 1040-1042 as amended, 1047-1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)): *It is ordered*, That Part 3 be amended in Subpart B by adding new § 3.207 to read as follows:

§ 3.207 Nutrition labeling of restaurant foods.

A nutrition claim or nutrition information concerning a combination of restaurant foods, e.g., the total nutritional value of a meal consisting of a hamburger, french fries, and milk shake, may be included in advertising and/or in labeling (other than labels), without causing nutrition information to be required on the label(s) of each article of food: *Provided*, That complete nutrition

information for the combination of foods (the combination as an entity without the nutritional value of each article being specified) in the format established by § 1.17(c) of this chapter is effectively displayed to the customer both when he orders the food and when he consumes the food. This statement of policy does not apply to food dispensed in automatic vending machines.

Effective date: This informal statement of policy shall be effective November 19, 1976.

(Secs. 201, 403, 701(a), 52 Stat. 1040–1042 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321, 343, 371(a)).)

Dated: November 12, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-34137 Filed 11-18-76;8:45 am]

[Docket No. 76C-0454]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Yellow No. 7 for Use In Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Yellow No. 7 for use in externally applied drugs and cosmetics; effective December 20, 1976; objections by December 20, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 34) for the "permanent" listing of D&C Yellow No. 7 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, DC 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, DC 20005); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, DC 20006), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Yellow No. 7 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Yellow No. 7 for use in externally applied drugs and cosmetics under new §§ 8.4177 and 8.7257 (21 CFR 8.4177 and 8.7257). The provisional listing of D&C Yellow No. 7 for use in externally applied drugs and cosmetics under § 8.501(b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 20, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list D&C Yellow No. 7 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Yellow No. 7 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 8.501(b) (21 CFR 8.501(b)).

This order establishes specifications for the certification of batches of D&C Yellow No. 7 that are more restrictive than those currently prescribed under § 9.130 (21 CFR 9.130). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specifications currently prescribed in § 9.130 become obsolete upon the effective date of new §§ 8.4177 and 8.7257. However, it is necessary to retain § 9.130 to provide for the use of the color additive in lakes. Accordingly, § 9.130 is revised to reference the identity nomenclature and specifications prescribed by § 8.4177.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), (d))) and transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 are amended as follows:

1. In part 8:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 *Provisional lists of color additives*, the entry for D&C Yellow No. 7 for use in externally applied drugs and cosmetics is deleted.

§ 8.502 [Amended]

b. In paragraph (b)(1) of § 8.502 *Termination of provisional listings of color additives*, the reference to D&C Yellow No. 7 is deleted, and the entry for D&C Yellow No. 7 in the undesignated paragraph that follows paragraph (b)(3) is also deleted.

§ 8.503 [Amended]

c. In paragraph (a) of § 8.503 *Temporary tolerances*, the reference to D&C Yellow No. 7 is deleted.

d. In Subpart E, new § 8.4177 is added to read as follows:

§ 8.4177 D&C Yellow No. 7.

(a) *Identity.* (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Subpart F of this part for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.
Matter insoluble in alkaline water, not more than 0.5 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-(2,4-Dihydroxybenzoyl benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 94 percent.

(c) *Uses and restrictions.* D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this part.

e. In Subpart G, new § 8.7257 is added to read as follows:

§ 8.7257 D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4177(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.130 to read as follows:

§ 9.130 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4177(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 20, 1976 file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above-mentioned office during working hours, Monday through Friday.

Effective date: This order shall become effective December 20, 1976 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), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note))

Dated: November 12, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-33991 Filed 11-18-76;8:45 am]

[Docket No. 76C-0455]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Yellow No. 8 for Use In Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Yellow No. 8 for use in externally applied drugs and cosmetics; effective December 20, 1976; objections by December 20, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 34) for the "permanent" listing of D&C Yellow No. 8 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, DC 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, DC 20005); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, DC 20006), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Yellow No. 8 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Yellow No. 8 for use in externally applied drugs and cosmetics under new §§ 8.4179 and 8.7259 (21 CFR 8.4179 and 8.7259). The provisional listing of D&C Yellow No. 8 for use in externally applied drugs and cosmetics under § 8.501 (b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 20, 1976 unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list D&C Yellow No. 8 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Yellow No. 8, will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 8.501(b) (21 CFR 8.501(b)).

This order establishes specifications for the certification of batches of D&C Yellow No. 8 that are more restrictive than those currently prescribed under § 9.131 (21 CFR 9.131). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specifications currently prescribed in § 9.131 become obsolete upon the effective date of new §§ 8.4179 and 8.7259. However, it is necessary to retain § 9.131 to provide for the use of the color additive in lakes. Accordingly, § 9.131 is revised to reference the identity nomenclature and specifications prescribed in § 8.4179.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 are amended as follows:

1. In part 8:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 *Provisional lists of color additives*, the entry for D&C Yellow No. 8 for use in externally applied drugs and cosmetics is deleted.

§ 8.502 [Amended]

b. In § 8.502 *Termination of provisional listing of color additives*, paragraph (b) (3) is deleted, and the entry for D&C Yellow No. 8 in the undesignated paragraph that follows paragraph (b) (3) is also deleted.

§ 8.503 [Amended]

c. In paragraph (a) of § 8.503 *Temporary tolerances*, the reference to D&C Yellow No. 8 is deleted.

d. In Subpart E, new § 8.4179 is added to read as follows:

§ 8.4179 D&C Yellow No. 8.

(a) *Identity.* (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 may contain only those diluents that are suitable and that are listed in Subpart F of this part for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 8 shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in alkaline water, not more than 0.3 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(2,4-Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Yellow No. 8 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Subpart A of this part.

e. In Subpart G, new § 8.7259 is added to read as follows:

§ 8.7259 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to

the requirements of § 8.4179 (a) (1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.131 to read as follows:

§ 9.131 D&C Yellow No. 8.

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 8.4177 (a) (1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 20, 1976 file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above-mentioned office during working hours, Monday through Friday.

Effective date: This order shall become effective December 20, 1976 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), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: November 12, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76–33992 Filed 11–18–76;8:45 am]

[Docket No. 76C–0426]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Red No. 17 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Red No. 17 for use in externally applied drugs and cosmetics; effective December 20, 1976, objection by December 20, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 39) for the "permanent" listing of D&C Red No. 17 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, DC 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, DC 20005); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, DC 20006), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Red No. 17 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Red No. 17 for use in externally applied drugs and cosmetics under new §§ 8.4116 and 8.7179 (21 CFR 8.4116 and 8.7179). The provisional listing of D&C Red No. 17 for use in externally applied drugs and cosmetics under § 8.501(b) (21 CFR 8.501 (b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 20, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list D&C Red No. 17 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Red No. 17 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 8.501(b).

This order establishes specifications for the certification of batches of D&C Red No. 17 that are more restrictive than those currently prescribed under § 9.162 (21 CFR 9.162). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specifications currently prescribed in § 9.162 become obsolete upon the effective date of new §§ 8.4116 and 8.7179. However, it is necessary to maintain § 9.162 to provide for the use of the color additive in lakes. Accordingly, § 9.162 is revised to reference the identity nomenclature and specifications prescribed by § 8.4116.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. In part 8;

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 *Provisional lists of color additives,* the entry for D&C Red No. 17 for use in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4116 is added to read as follows:

§ 8.4116 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[[4-(phenylazo)phenyl]azo] - 2 - naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 may contain only those diluents that are suitable and that are listed in Subpart F of this part as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 17 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C), not more than 5 percent.
Matter insoluble in both toluene and water, not more than 0.5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Aniline, not more than 0.2 percent.
4-Aminoazobenzene, not more than 0.1 percent.
2-Naphthol, not more than 0.2 percent.

1-(Phenylazo)-2-naphthol, not more than 3 percent.
1 - [[2-(phenylazo)phenyl]azo]-2-naphthalenol, not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 17 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Subpart A of this part.

c. In Subpart G, new § 8.7179 is added to read as follows:

§ 8.7179 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 8.4116 (a) (1) and (b).

(b) *Uses and restrictions.* D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.162 to read as follows:

§ 9.162 D&C Red No. 17.

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 8.4116 (a) (1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 20, 1976 file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday thru Friday.

Effective date. This order shall become effective December 20, 1976 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), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: November 12, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76–33994 Filed 11–18–76;8:45 am]

[Docket No. 76C–0427]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Green No. 8 for Use In Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Green No. 8 for use in externally applied drugs and cosmetics; effective December 20, 1976; objections by December 20, 1976.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21200) stated that a petition (CAP 9C0098) for the "permanent" listing of D&C Green No. 8 as a color additive for use in externally applied drugs and cosmetics had been filed by the Procter & Gamble Co., Toilet Goods Division, 6000 Center Hill Rd., Cincinnati, OH 45224. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Green No. 8 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health.

This order "permanently" lists D&C Green No. 8 for use in externally applied drugs and cosmetics under new §§ 8.4072 and 8.7102 (21 CFR 8.4072 and 8.7102). The provisional listing of D&C Green No. 8 for use in externally applied drugs and cosmetics under § 8.501 (b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), and the corresponding regulation, § 9.106 (21 CFR 9.106), in Part 9 that prescribes specifications for the certification of D&C Green No. 8 will be deleted when this order becomes effective on December 20, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing and § 9.106 will continue in effect until December 31, 1976 unless terminated or extended by regulation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Sec. 706 (b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Pub. L. 86–618, Title II, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. In Part 8:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 Provisional lists of color additives, the entry for D&C Green No. 8 for use in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4072 is added to read as follows:

§ 8.4072 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo] - 4 - hydroxy-1-naphthalenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in Subpart F of this part for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
5 - Amino - 2,4 - dimethyl - 1 - benzenesulfonic acid, sodium salt, not more than 0.2 percent.
4 - Hydroxy - 1 - naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(e) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in Subpart A of this part.

c. In Subpart G, new § 8.7102 is added to read as follows: