

**FEDERAL TRADE COMMISSION****[16 CFR Part 305]****Labeling and Advertising of Consumer Appliances; Scheduling of Oral Presentation Before Commission Concerning Rule Recommended by Staff****AGENCY:** Federal Trade Commission.**ACTION:** Scheduling of oral presentation before Commission concerning Rule Recommended by staff.

**SUMMARY:** The Commission is ready to begin considering final action on its proposed statutory rule governing the labeling and advertising of consumer appliances. (43 FR 31806, July 21, 1978; 43 FR 41410, September 18, 1978; 44 FR 10076, February 16, 1979; 44 FR 32013, June 4, 1979). To provide interested parties with the fullest possible opportunity to make their views known to the Commission, oral presentations will be made at an open meeting of the Commission on June 26, 1979 at 2:00 p.m. in Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580. Invitations to participate in this proceeding have been extended to ten parties who were chosen because of their previous participation in the proceeding and because they represent a variety of industry, consumer, and governmental interests.

**DATE:** Oral presentations will begin at 2:00 p.m. on June 26, 1979.

**ADDRESS:** The presentations will take place at an open Commission meeting in Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, Washington, D.C. 20580.

**FOR FURTHER INFORMATION CONTACT:** Andrew I. Wolf, Attorney, Room 6009, Star Building, Federal Trade Commission, Washington, D.C. 20580, (202) 724-1453.

Carol M. Thomas,  
Secretary.

[FR Doc. 79-19616 Filed 6-21-79; 8:45 am]

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**DEPARTMENT OF LABOR****Employment and Training Administration****[20 CFR Part 676]****Comprehensive Employment and Training Act: Regulations Concerning Sectarian Activities Under the Act**

Note.—This document originally appeared in the Federal Register for Wednesday, June

20, 1979. It is reprinted in this issue to meet requirements for publication on an assigned day of the week. (See CFR notice 41 FR 32914, August 6, 1976.)

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes to revise the regulation at 20 CFR § 676.71, published on April 3, 1979, at 44 FR 20028, concerning sectarian activities under the Comprehensive Employment and Training Act (CETA). The purpose of this document is to clarify when funds under the Act may be used with respect to religious elementary and secondary schools, and other religious activities.

**DATES:** Interested persons are invited to submit written comments on or before July 23, 1979. The primary impact of the proposed rule will be on religiously affiliated elementary and secondary schools. Since it is necessary to provide clear guidance to grantees as soon as possible, the comment period has been limited to 30 days.

**ADDRESS:** Written comments should be addressed to the Assistant Secretary for Employment and Training, U.S. Department of Labor, Room 5014—Patrick Henry Bldg., 601 D Street, N.W., Washington, D.C. 20213. Attention: Mr. Robert Anderson, Administrator, Office of Comprehensive Employment Development.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert Anderson, at Telephone No. (202) 376-6254.

**SUPPLEMENTARY INFORMATION:** Final regulations implementing Titles I, II, VI, and VII of the Comprehensive Employment and Training Act (CETA), as amended by the CETA Amendments of 1978 (Pub. L. 95-524), were published at 20 CFR Parts 675-679 in the Federal Register on April 3, 1979 (44 FR 19990). Section 676.71(b) of 20 CFR Part 676 sets forth the statutory prohibitions regarding sectarian activities, and states that the Department of Labor would be publishing proposed regulations to further clarify these provisions in the near future. Sections 121(a)(2) and 123(g) of CETA (92 Stat. 1934 and 1943) establish certain limitations on the use of CETA funds in connection with religious activities. These provisions, however, do not resolve many of the questions that may arise with regard to CETA activities at religiously affiliated elementary or secondary schools. They

must also be interpreted in light of the standards established by the Supreme Court under the First Amendment. In light of this, and in keeping with the remedial purpose of the statute, the following rules are being proposed.

Accordingly, it is proposed to revise section 676.71 of Chapter V of Title 20, Code of Federal Regulations, to read as follows:

**§ 676.71 Sectarian activities.**

(a) No funds under the Act may be used to support any religious or anti-religious activity. However, this does not preclude religious organizations from administering or operating CETA programs or from the use of the facilities of religious organizations for the operation of such programs within the limits set forth in the Act or other applicable law.

(b) Section 121(a)(2) of the Act (29 U.S.C. 823(a)(2)) provides that:

"Participants shall not be employed on the construction, operation, or maintenance of so much of any facility as is used or will be used for sectarian instruction or as a place of religious worship."

Section 123(g) of the Act (8 U.S.C. 825(g)) provides that the Secretary, by regulation, shall establish such standards and procedures for recipients of funds under the Act as are necessary to assure against program abuses including, but not limited to, the use of funds for religious or antireligious activities. Pursuant to these statutory provisions, a participant may not be employed by a religiously affiliated elementary or secondary school to perform the functions of a teacher, librarian, guidance counselor, janitor or maintenance worker, clerical worker or teacher aide, unless the participant is performing functions or working in programs such as those described in paragraphs (c) or (e) of this section. In applying this prohibition, it is the function actually to be performed by the participant that is to be regarded as controlling, rather than the technical job title given the participant. For example, it would be permissible for a participant (whatever the participant's title) to be employed as an escort to bring students safely to and from school.

(c) Religiously affiliated elementary or secondary schools, may subject to supervision by the prime sponsor, employ participants in programs such as adult education, recreation, summer



programs or other similar activities including remedial tutorial activities, provided that such programs are not a part of the regular school curriculum (including summer school), are open to the community at large, and in which the community is encouraged to participate, and provided further that such programs do not involve religious activities.

(d) A prime sponsor, or a subrecipient which is not a religious organization, may outstation a participant to a religiously affiliated elementary or secondary school to provide remedial education services which do not involve religious activities, provided that such services are not part of the regular school curriculum (including summer school), that such services also are made available to public school students in the area and that the prime sponsor has established procedures adequate to insure public supervision.

(e) Participants may be employed by a religiously affiliated elementary or secondary school in the following capacities, or performing functions characteristic of these capacities:

(1) Cafeteria work or other work directly related to the provision of food services to students including clerical, custodial or maintenance work related to such services.

(2) Diagnostic or therapeutic speech and hearing services including clerical work related to such services.

(3) Nursing or health services or any other activities relating to the health or safety of students (e.g. assisting on school buses or in escorting children to and from school, acting as attendance clerks or school crossing guards, removing asbestos hazards or performing other similar emergency service relating to the health or safety of students), including clerical work related to such services.

(4) Any functions (including secretarial or clerical activities) where such activities are limited to providing support services for the administration of federally funded or regulated programs made applicable to religious institutions.

(5) Functions performed with respect to the administration and grading of State-prepared examinations.

(6) Custodial child care after school hours provided the participant is not providing educational services.

(f) The Secretary may consider, on a case-by-case basis, applications for participation in programs other than those set forth in paragraphs (c), (d), and (e) of this section and may approve those applications for programs that are not inconsistent with the requirements of this section.

Signed at Washington, D.C., this 18th day of June 1979.

Ray Marshall,  
Secretary of Labor.

[FR Doc. 79-19419 Filed 6-19-79; 8:45 am]

BILLING CODE 4510-30-M

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

#### [21 CFR Part 74]

[Docket No. 79N-0042]

#### Lakes of Color Additives; Termination of Proposal

AGENCY: Food and Drug Administration.

ACTION: Termination of proposal.

**SUMMARY:** The Food and Drug Administration (FDA) is terminating a notice of proposed rulemaking concerning lakes of color additives because of the long interval of time since the issuance of the proposal and because of the need for more information on lakes of color additives.

#### FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5740.

**SUPPLEMENTARY INFORMATION:** A notice was published in the Federal Register of May 11, 1965 (30 FR 6490) proposing the listing of and specifications for lakes of color additives then listed under Subparts A, B, and C of Part 8 of the color additive regulations (21 CFR Part 8) (recodified to Part 74 (21 CFR Part 74) by publication in the Federal Register of March 22, 1977 (42 FR 15553)). The proposed regulations would have replaced the provisional regulations for lakes of color additives under former Part 9 (21 CFR Part 9) (recodified to Parts 81 and 82 (21 CFR Parts 81 and 82)). However, because of the absence of any listings for color additives in Subparts A, B, and C, the order was never finalized.

Because several colors are now listed under Subparts A, B, and C of Part 74, it is appropriate to promulgate a final order on lakes of color additives. However, because of the long interval of time since the original proposal and because several additional questions have arisen, FDA concludes that a new proposal is necessary. Published elsewhere in this issue of the Federal Register is a notice of intent requesting comments and information that the agency will consider in developing a

new proposal for the regulation of lakes of color additives. Therefore, the proposed rulemaking in the Federal Register of May 11, 1965 (30 FR 6490) on this matter is no longer appropriate and is terminated.

This action is taken under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

Dated: June 14, 1979.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 79-19313 Filed 6-21-79; 8:45 am]

BILLING CODE 4110-03-M

#### [21 CFR Part 74]

[Docket No. 79N-0043]

#### Lakes of Color Additives; Intent To List

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent to Propose Rules.

**SUMMARY:** The Food and Drug Administration (FDA) announces its intention to propose regulations concerning lakes of color additives. A review of the comments on an earlier FDA proposal and the available data indicate additional information is needed before final regulations can be issued. This notice discusses the additional information that is needed and, in particular, requests comment on (1) definition and nomenclature of lakes, (2) safety of lakes, and (3) specifications for lakes. This notice also addresses comments on the earlier proposal and evaluates them for consideration as part of the new proposal on lakes.

**DATE:** Comments and information by August 21, 1979.

**ADDRESS:** Written comments and information to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

#### FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5740.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Colors are used in three forms in the coloring of foods, drugs, and cosmetics. The principal form used in coloring



foods and, to lesser extents, drugs and cosmetics is the basic chemical, i.e., the "straight" color. A second form is created by mixing the straight color with various diluents to form a color additive mixture. The third form in which colors are used is as lakes. These are combinations in which a straight color is closely bound to a substrate to form an insoluble pigment. In § 70.3(1) of the color additive regulations (21 CFR 70.3(1)), the term "lake" is defined as "a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process."

The majority of lakes marketed today are manufactured with synthetic organic colors that are subject to certification and are themselves subject to certification. The first step in their production, as discussed in more detail below, is to absorb the soluble color onto an insoluble substrate to form a coloring material, the lake of the color, that is insoluble. These colored lake particles are washed, dried, and then finely ground before marketing. The color intensity desired in the finished lake can be controlled by varying the amount of pure color employed in its preparation. The concentration of pure colors usually employed in lakes ranges from 12 to 40 percent. When dispersed in dry product mixes, the lake particles impart an evenness and uniformity of color that cannot be obtained from the organic colors in the pure crystalline state. Likewise, in dry mixes such as cake mixes pure colors will cause streaking and spotting when water is added.

For many applications, lakes offer additional advantages over pure colors. Because the color is chemically bonded to its substrate, the colored lake exhibits increased light stability (as used in cake icings and cookie fillings), increased resistance to heat degradation (as used in imitation chocolate or butterscotch chips), and reduced color migration (as used in striped candy canes). These properties permit improved color control through thermal processing and can extend color shelflife if the product is exposed to natural or artificial lighting.

Lakes were not permitted in food, drug, and cosmetic applications until 1959 when FDA began certifying them for use as primary colorants. Before 1959, only pure colors could be used in food, drugs, and cosmetics. In 1964, 5 years after lakes were permitted for use, only 7.5 percent of all colors certified were certified lakes. By 1978, this percentage had increased to 25.

FD&C lakes are currently used in numerous food products including cake mixes, breakfast drinks, colored salt or sugar, processed cheese, pet foods, and desserts. FD&C and D&C lakes are used in coloring the coatings of ingested drug tablets. In cosmetics, FD&C, D&C, and Ext. D&C lakes are used as primary colorants in lipsticks, rouges, soap, face powders, and nail lacquers.

In the manufacture of FD&C lakes, the first step of the laking process generally involves the production of an alumina slurry. The production may be accomplished by the careful precipitation of hydrated alumina from an aluminum sulfate solution by the addition of a sodium carbonate solution or sodium hydroxide. An aqueous solution of the dye is then mixed with the resulting alumina slurry to give a partially precipitated, or "laked," product as some of the water-soluble dye is adsorbed onto the alumina. The laking is completed by the addition of aluminum chloride, resulting in the production of the aluminum salt of the dye that is strongly adsorbed on the alumina particles.

Much the same process can be accomplished with D&C lakes using other substrata and salt forms to produce pigments insoluble in water or oil. In addition, D&C lakes may be produced from one or a number of colors to yield a variety of shades. The concentration of the straight color can also be varied to produce the desired shade.

Lakes are currently regulated under Parts 81 and 82 of the color additive regulations (21 CFR Parts 81 and 82). They are permitted for use within the specific restrictions prescribed for the various colors that they may contain. All lakes are now produced with colors that are subject to certification. FD&C lakes are required to be manufactured from previously certified colors, while D&C and Ext. D&C lakes may be made from either previously certified or uncertified batches of colors. However, each of these types of lakes must be certified before it may be used in food, drugs, or cosmetics.

To establish "permanent" regulations for lakes, a notice was published in the Federal Register of May 11, 1965 (30 FR 6490) proposing the listing of and specifications for lakes of color additives listed under Subparts A, B, and C of Part 74 (21 CFR Part 74) (formerly Part 8 (21 CFR Part 8), before recodification published in the Federal Register of March 22, 1977 (42 FR 15553)). Five comments were received which recommended changes in the proposal. However, because of the

absence of any listings for color additives in Subparts A, B, and C of Part 74 at that time, the order was never finalized, and the provisional regulations for lakes under Parts 81 and 82 have remained in effect.

In recent years, several colors have become "permanently" listed under Subparts A, B, and C of Part 74, and the issuance of a final order on the lakes proposal would now appear appropriate. However, because of the long time interval since the original proposal and because several additional questions have arisen, a new proposal is appropriate. Elsewhere in this issue of the Federal Register, the agency is terminating the original proposal and in this notice is requesting information that will be considered in the development of a new proposal for the regulation of lakes. The information may be submitted by current petitioners as amendments to existing color additive petitions that propose the use of lakes, or in the form of a new petition in the format outlined in § 71.1 (21 CFR 71.1). Because of the issuance of the earlier proposal, FDA concluded that it should provide public notice concerning the need for additional data. In addition, as part of the development of a new lakes proposal, the five comments submitted in response to the original proposal and discussed below will be considered.

## II. Comments on Original Proposal

1. Three of the five comments on the original lakes proposal recommended revising the proposed regulations for Subparts B and C to provide for the use of one or more previously certified color additives in the preparation of lakes for drug and cosmetic use.

The agency concludes that this recommendation has merit and will be considered further in the development of the new proposal on lakes.

2. One of the comments recommended revising the specifications for lakes of color additives to provide that the soluble chlorides and sulfates (as sodium salts) and moisture be not greater than the proportion that is related by percent to the permitted level in the pure colors, as long as the level of acceptability is at least 3 percent.

FDA believes that, although the suggested revision concerning the presence of soluble chlorides and sulfates is reasonable, specification for soluble chlorides and sulfates may not be necessary. Therefore, the agency is considering deleting such a requirement in the new lakes proposal (see Part III. C. of this document, "Development of a Lakes Proposal—Specifications").



3. The same comment requested that specifications for ratios of "uncombined intermediates/pure color" and "subsidiary colors/pure color" in lakes be not greater than the ratios permitted in the specifications for the pure color additive, as long as the level of acceptability is at least 0.2 percent.

The agency concludes that this proposed revision is unacceptable because it could result in a lake having a higher percentage of impurities relative to the color content than would be permitted in the parent straight color. For example, if a pure color contained intermediates or subsidiaries in the maximum amount allowable (say 0.3 percent), then a lake containing 50 percent of the color would presumably contain 0.15 percent. But with the proposed revision, the lake could contain up to 0.2 percent, which would be an amount higher proportionally than is permitted in the pure color. Unless the safety of higher levels of intermediates and subsidiary colors can be assured, the suggested revision will not be considered further.

4. Another comment suggested that, instead of establishing new categories, FDA classify lakes as color additive mixtures and list permitted substrates in appropriate sections as diluents for color additive mixtures.

This revision is directly related to the definition of a lake discussed below (see Part III. A., "Development of a Lakes Proposal—Definition and Nomenclature"). FDA does not agree that all lakes should be classified as color additive mixtures but does find that some apparently are closer to being simple mixtures than to what has been described as a lake. The suggested revision, therefore, will be considered in combination with the information requested below on the definition of a lake.

5. The same comment also proposed to reduce fees for certifying lakes and to simplify the label declaration for lakes in color additive mixtures by simplifying the label requirements for color additive mixtures.

FDA advises that the suggested revisions are not acceptable because the agency believes that the current fees for certification of lakes are appropriate and that the current method for labeling of color additive mixtures is necessary to provide for their safe use.

### III. Development of a Lakes Proposal

There are three general areas of concern in the development of a new proposal for the regulation of lakes: (A) Definition and nomenclature, (B) safety, and (C) specifications. As discussed

below, the agency is requesting information and comment on each of these three areas for consideration in the issuance of a new proposal on lakes.

#### A. Definition and Nomenclature

1. As noted above, the term "lake" refers to a substance formed by the chemical or physical interaction (adsorption, chelation, salt formation, etc.) of a straight color with an appropriate substratum and does not include any combination of ingredients made by a simple mixing process. A review of the various processes that are used to make what are referred to as lakes had disclosed some exceptions to this definition. The initiation of the formation of a lake generally occurs with the precipitation of a water-soluble dye in the presence of the substratum. In certain instances with (1) dyes that are insoluble metal salts and (2) dyes that are sparingly soluble in water and that lack salt-forming functional groups, the extension of the color on the substratum is more similar to a mixing process with little, if any, resulting chemical interaction. Although these types of substances, where there is little or no interaction, have generally been known by the industry as "extended toners," the materials have been classified and treated as "lakes" under the color additive regulations.

FDA requests comment and information concerning the continuation of the current definition of lakes or the possibility of dividing the differing types of pigments discussed above into specific categories with separate provisions and specifications for each. In the absence of comments to the contrary, the agency intends to exclude mixtures such as the extended toners from the definition of lakes.

2. The various substrata and procedures that may be used in producing lakes are described separately in §§ 82.51 *Lakes (FD&C)*, 82.1051 *Lakes (D&C)*, and 82.2051 *Lakes (Ext. D&C)* (21 CFR 82.51, 82.1051, and 82.2051). The agency is considering additional changes in the identifications given in these sections of the regulations and specifically requests comment on the following possible changes:

(i) One modification would provide for lakes formed by interaction between the substratum and nonsalt colors. Currently, lakes may be prepared only from colors that are salts.

(ii) When lakes are formed by interaction with colors that are salts, allowance would be provided for some simultaneous incorporation of the nonsalt form of the color and vice versa.

(iii) Although the current regulations permit the use of calcium or aluminum as the metallic cation used in the preparation of FD&C lakes, calcium FD&C lakes have not been submitted for certification. Because of this lack of interest by manufacturers, the agency is considering the deletion of calcium as one of the metallic cations permitted in FD&C lakes.

(iv) For FD&C lakes, FDA requests comment on the following definition, which would incorporate revisions (i) through (iii) above: "A lake is designated FD&C if made by combining one or more previously certified FD&C colors with the basic aluminum cation in the presence of the substratum hydrated alumina."

3. The agency also requests comments on a system of nomenclature for lakes because of several problems with the current system:

(i) D&C lakes may have an identical designation but differ in actual composition because of differences in the substrata. For example, the name of a lake prepared by extending D&C Green No. 5 upon titanium dioxide is "D&C Green No. 5—Sodium Lake." Currently, the same name is given to a lake prepared by extending D&C Green No. 5 upon calcium carbonate.

(ii) Lakes identical in composition may have different designations. For example, the aluminum salt of D&C Red No. 9 extended on alumina would be identical to the aluminum salt of D&C Red No. 8 extended on alumina because the parent straight colors differ only in that one is a sodium salt and the other is a barium salt; the lake designation, however, would differ, with one being "D&C Red No. 8—Aluminum Lake," and the other "D&C Red No. 9—Aluminum Lake."

(iii) No provision exists for naming lakes prepared from colors with no salt-forming groups.

The agency requests comment and suggestions concerning a system of nomenclature for lakes that will resolve problems such as those discussed above. In the absence of any comments, the agency intends to require that the nomenclature for lakes specifically identify the form of the color that is used as well as the substratum.

#### B. Safety

1. To ensure safety, the specifications for "intermediates" and "subsidiary colors" must be established for lakes prepared from uncertified colors or colors produced in situ. As discussed below, such specifications may also be necessary for lakes prepared from previously certified colors if there is a



possibility for significant deterioration of the colors during the laking process. In these cases, the proportionality of intermediates and subsidiaries should relate to those levels observed in the pure certified colors for which specifications and regulations have been published. The agency, therefore, is considering the following guidelines:

Percent of pure dye in lake	Allowable amounts of intermediates and subsidiaries—given as a percentage of the amount allowable in the pure color
More than 75.....	100
50 to 75.....	75
25 to 50.....	50
25.....	25

For example, these guidelines would apply for FD&C Yellow No. 5, which has a specification of 1.0 percent for subsidiary dyes, as follows:

Percent of FD&C Yellow No. 5 in lake	Allowable amounts of subsidiaries in lake (percent)
More than 75.....	1.0
50 to 75.....	0.75
25 to 50.....	0.50
25.....	0.25

2. The agency is concerned about the safety data and identification of some substrata used for lakes:

(i) Although talc is regulated in several instances as a food additive and also for drug use, there has been some concern about the asbestos content of talc and its safety following ingestion. FDA published a proposal in the Federal Register of September 28, 1973 (38 FR 27076) that would have required talc to be free of asbestos fiber to the maximum extent practicable. After receiving comments on the proposal, the agency concluded that a prohibition of asbestos-containing talc as a food or food additive or in drugs or drug ingredients was unwarranted due to lack of sufficient data (see the Federal Register of March 14, 1975 (40 FR 11865)). The data on whether the presence of asbestos as a contaminant posed any health hazard from these uses of talc were inconclusive. Additionally, adequate analytical methods were not available for measuring the level of asbestos in talc. The agency is still not aware of any data that would support the establishment of specifications for asbestos in talc. Of course, talc used for lakes should be as free of asbestos as possible under good manufacturing practice.

(ii) Rosin and clay are currently used as substrata in D&C and Ext. D&C lakes. However, these substrata are not well defined chemically. Because there may be great differences in the composition of either of these materials as they occur

in nature, standard specifications for the clay and rosin used in the formulations of lakes should be established. These specifications should control the composition of the materials that can be used. The agency, therefore, is requesting the submission of suggested standard specifications for rosin and clay used in the production of D&C and Ext. D&C lakes.

Comment on the merit of establishing specifications for the remaining substrata is also requested. Such specifications might be by reference to another food or color additive regulation involving the substratum. For example, specifications for calcium carbonate used in lakes could reference § 73.1070, which contains specifications for calcium carbonate used in drugs.

### C. Specifications

1. Problems have arisen in the spectrophotometric method for the determination of the pure dye content in lakes. In this method of analysis, the colors in the lakes are solubilized under certain conditions and the spectra recorded. The spectra are then compared to "standard" spectra of the colors in order to determine the percent pure color in the lake. A problem arises in that it is not clear that the current standard absorptivity values for each dye were determined under the same conditions being used for the solubilization of the dye in the lake. Therefore, the FDA requests submission of available methods for the spectrophotometric determination of pure color content in lakes.

2. The agency is considering not requiring specifications for intermediates and subsidiary colors in lakes prepared from previously certified colors. If previously certified colors are used in the preparation of lakes, the percent of intermediates and subsidiary colors in the lakes, based on pure dye content, should presumably be at levels proportional to those in the original batch of pure dye. The agency, however, is concerned about the absence of data demonstrating the stability of previously certified colors during the laking process. If significant deterioration of the color were to occur, the percentage of intermediates or subsidiary colors, based on pure dye content, could be at levels higher than in the original batch. If data are submitted demonstrating the stability of previously certified colors during the laking process, the FDA intends to delete the specifications for intermediates and subsidiary colors for lakes when prepared from certified batches of colors.

3. Satisfactory methods for the determination of total intermediates in lakes have not been developed. Current methods detect only "free" intermediates and cannot detect those that, like the dye, are "laked." The lack of methodology for total intermediates in lakes does not pose a problem for lakes produced from previously certified batches of colors if there is no degradation of the color during the laking process. In this case, the color used to produce the lake is a discrete batch that can itself be analyzed for total intermediates.

Likewise, no problem occurs in cases in which the lake is produced from a finished batch of color, albeit uncertified. However, many lakes are produced in situ, such that the color never appears as a discrete unit in the process. In these cases, the processing of the lake proceeds directly from the original synthesis of the color to the formation of its lake with no interruption in the manufacturing process. Excessive levels of intermediates could be used during the process, become "laked," and, therefore, escape detection during the certification process because of the absence of methodology for determining total intermediates in lakes. High levels of such "laked" intermediates may then present a health hazard if they become available to the body following ingestion or other uses. Additional problems encountered with the analysis of intermediates include interference from substrata (benzoate and rosin) and decomposition of the pure color during analysis. The problem is further complicated in attempting to analyze for intermediates in lakes containing mixtures of color additives. The agency is therefore requesting:

(i) The submission of methods of analysis for the determination of total intermediates in lakes prepared from a single color and in lakes prepared from mixtures of colors. If suitable methodology for total intermediates cannot be developed, an alternative approach to addressing the problem of possible high levels of "laked" intermediates would be to present data demonstrating that the "laked" intermediates do not become available from the use of the lake. Without appropriate data to allay the concerns over "laked" intermediates, it may be necessary to require that all lakes be produced from previously certified batches of colors or, at least, from discrete batches of colors.

(ii) The submission of methods of analysis for the determination of total intermediates in lakes using benzoate or



rosin as the substratum. Without acceptable methodology, it may be necessary to delete these as acceptable substrata.

4. Although methods for the determination of subsidiary colors in lakes of individuals color additives are available, they are not efficient and can be time consuming. Furthermore, methods are not available for the determination of subsidiaries in lakes formed from mixtures of colors. The agency is therefore requesting the submission of all available methods which have been developed for the analysis of subsidiary color in lakes, including subsidiaries in lakes of color additive mixtures.

5. The agency is aware that residues of chemicals occasionally used in the laking process, such as citrate, acetate, and various surfactants, may be present in the final product. Accordingly, FDA requests comment on the probability and/or amount of these types of residues incorporated into the finished lake.

6. Because of the difficulty in analysis and because of lack of health hazard, the agency is considering deleting specifications for soluble chlorides and sulfates in all types of lakes. FDA requests comment on the possible deletion of those specifications.

7. The following additional minor changes in the originally proposed specifications are being considered:

(i) Inclusion of a specification for mercury in FD&C, D&C, and Ext. D&C lakes;

(ii) Revision of the specification for "inorganic matter soluble in hydrochloric acid" to "matter insoluble in hydrochloric acid"; and

(iii) A separate specification for insoluble matter in FD&C Red No. 3 and other colors where the dye is insoluble in hydrochloric acid.

#### IV. Summary of Information Requested

The agency anticipates that a satisfactory response to the questions discussed in detail above will permit the preparation of a notice of proposed rulemaking concerning color additive lakes. The proposed rules will be restricted in their coverage to the extent that data are not submitted or are otherwise insufficient to support the safety of particular aspects of the use of lakes. For clarity's sake, the primary questions and types of information for which responses are being sought are summarized below. All responses to these questions or others mentioned above should be supported by appropriate data.

A. Definition and nomenclature.—1. Comments and information are requested concerning the continuation of the present definition of lakes. In what particular ways should the definition be changed and why?

2. Should the definition for lakes be revised to reflect the use of colors as toners or extended toners? Should these be considered to be lakes or should they be exempted from consideration as lakes; if not as lakes, how should they be regulated under the color additive amendments?

3. What specific changes should be made in defining how lakes are made? What processes should continue to be permitted or added? What processes should be deleted?

4. Comments and information are requested on the nomenclature that should be used to identify lakes.

B. Safety.—1. What specifications should be established for intermediate and subsidiary colors? How should these relate to the levels considered acceptable on the basis of toxicological tests? Are the guidelines proposed above for establishing limits on intermediates and subsidiary colors satisfactory?

2. What should be the data requirements for substrata as they relate to safety?

3. What specifications should be established for the naturally occurring substrata that would provide the strictest degree of chemical definition for these substances?

C. Specifications for color additive lakes.—1. Methods with appropriate validation data are requested for the determination of pure color content in lakes.

2. What specifications should be established for lakes that are produced from previously certified colors?

3. Methods for the determination of total intermediates in lakes should be submitted. These methods should be applicable to all types of lakes.

4. Should there be concern for total intermediates in lakes or should allowances be made for the presence of "laked" intermediates on the basis that they are not bioavailable?

5. What specifications should be established for lakes?

6. All available methods for the analysis of subsidiary colors in lakes should be submitted with appropriate validation data.

Interested persons may, on or before August 21, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this notice of intent

to propose regulations. Four copies of all comments should be submitted, except that individuals may submit single copies of comments, identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Comments and information that are considered trade secrets or otherwise confidential may be submitted (with those portions considered trade secret clearly identified as such) to Petitions Control Branch (HFF-334), Division of Food and Color Additives, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Dated: June 14, 1979.

William F. Randolph,  
Acting Associate Commissioner for  
Regulatory Affairs.

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#### [21 CFR Parts 184, 186]

#### Acetic Acid, Ammonium Acetate, Sodium Acetate, and Sodium Diacetate; Proposed GRAS Status

##### Correction

In FR Doc. 79-10109 appearing at page 19430 in the issue for Tuesday, April 3, 1979, make the following corrections:

(1) On page 19433, in the middle column, in § 184.1721, subparagraph (d) should read as follows:

"(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.007 percent for breakfast cereals as defined in § 170.3(n)(4) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 0.6 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter and for snack foods as defined in § 170.3(n)(37) of this chapter; 0.12 percent for jams and jellies as defined in § 170.3(n)(28) of this chapter and for meat products as defined in § 170.3(n)(29) of this chapter; 0.2 percent for soft candy as defined in § 170.3(n)(38) of this chapter; and 0.05 percent for soup and soup mixes as defined in § 170.3(n)(40) of this chapter and for sweet sauces as defined in § 170.3(n)(43) of this chapter."

(2) On page 19433, in the last column, in § 186.1005, in subparagraph (a), in the 7th line, "systhesis" should be corrected to read "synthesis".

(3) On page 19433, in the last column, in § 186.1005, in subparagraph (a), in the