FOR FURTHER INFORMATION CONTACT: Bronwen Mason Chaiffetz, Senior Counsel, Legal Division (202/452-3564).

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act analysis and Regulatory Impact analysis have not been included in this notice because the change effected by this amendment is technical in nature. These analysis are included in the **Federal Register** notice that accompanied the previous substantive amendments (48 FR 34016). The provisions of section 553 of Title 5, United States Code, relating to notice, public participation, and deferred effective date have not been followed in connection with this amendment because it is a technical one.

List of Subjects in 12 CFR Part 265

Authority delegations (Government agencies, Banks, banking, Federal Reserve System.

Pursuant to its authority under section 3(a), 4(c)(8) and 5(b) of the Bank Holding Company Act, and section 18(c) of the Federal Deposit Insurance Act (Bank Merger Act, 12 U.S.C. 1828(c)), the Board of Governors is amending its Rules Regarding Delegation of Authority (12 CFR 265). The regulations appearing in FR Doc. 83-20196 (48 FR 34016) are corrected by revising § 252.2(f)(22) (iv) and (v) and by adding paragraph (vi) as follows:

§ 265.2 Specific functions delegated to Board employees and to Federal Reserve Banks.

* * * * *

(f) * * *

(22) * * *

(iv) the application raises a significant policy issue or legal question on which the Board has not established its position; or

(v) with respect to bank holding company formations, bank acquisitions or mergers, the proposed transaction involves two or more banking organizations:

(A) that rank among a State's ten largest banking organizations in terms of total domestic banking assets; or

(B) each of which has more than $100 million of total deposits in banking offices in the same local banking market that, after consummation of the proposal, would control over 10 percent of total deposits in banking offices in that local market; or

(vi) with respect to nonbank acquisitions:

(A) the nonbanking activities involved do not clearly fall within activities that the Board has designated as permissible for bank holding companies under § 225.4(a) of Regulation Y; or

(B) the proposal would involve the acquisition by a banking organization that has total domestic banking assets of $1 billion or more of a nonbanking organization that appears to have a significant presence in a permissible nonbanking activity.[2]

Board of Governors of the Federal Reserve System, August 23, 1983.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 83-23545 Filed 8-29-83; 8:45 am]

BILLING CODE 6210-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release Nos. 33-6480; 34-20105; 35-23040; 39-846; IA-877; IC-13456]

Acceptance of Travel Reimbursement

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: Pub. L. 98-38 which became effective on June 6, 1983, grants to the Commission, subject to the adoption of rules to prevent conflicts of interest, the authority to accept from non-federal sponsors payment or reimbursement for expenses incurred by Commission members and staff in connection with participation at conferences and meetings. The Commission has adopted regulations to implement this authority.

EFFECTIVE DATE: August 30, 1983.

FOR FURTHER INFORMATION CONTACT: Myrna Siegel, Ethics Counsel, Office of the General Counsel, Securities and Exchange Commission, Washington, D.C. 20549, 202-272-2430.

SUPPLEMENTARY INFORMATION: Pub. L. 98-38, which became effective on June 6, 1983, grants to the Commission the authority to accept payment or reimbursement for expenses incurred by Commission members and staff in connection with participation at conferences and meetings. To implement this authority, the Commission has adopted regulations which establish a procedure for determining when and how the Commission will accept such payment or reimbursement. The regulations have a two-fold purpose: To eliminate real or apparent conflicts of interest in connection with the acceptance of payments or reimbursements and to create administrative procedures for determining when reimbursement will be accepted by the Commission and the mechanism for public disclosure of such acceptance.

Discussion

The Commission has generally deemed participation by its members and employees in continuing legal education programs, securities industry conferences, accounting profession meetings, and similar functions as important factors in fostering compliance with and understanding of the federal securities laws. While sponsoring organizations often have been willing to pay the actual expenses of Commission members and employees invited to participate in meetings and conferences of an educational nature, interpretations of federal statutes prohibited acceptance for travel by Commissioners from all sponsors, except those which are tax-exempt pursuant to 26 U.S.C. 501(c)(3). Additionally, the prohibitions imposed by the Foreign Gifts and Decorations Act, 5 U.S.C. 7342, have restricted members of the Commission from accepting reimbursement for assistance in various types of proceedings rendered at the behest of foreign governments.

These constraints on accepting such reimbursements, coupled with the restrictions on the size of the Commission's travel budget, have compelled members of the Commission to limit their participation in educational and similar programs. The authority recently granted to the Commission will permit Commissioners to continue to engage in educational functions, while placing the burden of the cost of such participation on the sponsors, rather than the federal government.

The rules which the Commission has adopted to implement its new authority have been carefully tailored to avoid any real or apparent conflicts of interest. The rules contemplate that all travel by Commission members and staff for participation in educational meetings will be pursuant to the procedures detailed in these regulations. The regulations continue the Commission's current policy of prohibiting acceptance of any payment or reimbursement from entities which are registered with the Commission or directly or indirectly regulated by the Commission. Indirect regulatees are affiliates, parents and subsidiaries of regulated entities. Moreover, no reimbursement will be accepted by the Commission in connection with a conference which is sponsored by a registered or regulated entity, whether or not that sponsor is

[2] While other situations may involve the issue of significant presence, the Board regards, as a general guideline, any company that ranks among the 20 largest independent firms in any industry as having a significant presence.

directly paying for expenses. The determination as to whether payment or reimbursement will be accepted by the Commission from an association predominantly composed of entities regulated by the Commission will be made by the Commission's Chairman.

Except with respect to programs sponsored by groups predominantly composed of entities regulated by the Commission, the decision as to whether the Commission will accept payment or reimbursement in connection with staff member participation at a particular meeting will be made by the Commission's Executive Director. Notice of all determinations with respect to acceptance of payment or reimbursement by the Commission will be placed in a public file in the Commission's Public Reference Room, Washington, D.C., and a compilation of payments or reimbursements accepted will be published quarterly in the *SEC Docket*.

Regulatory Flexibility Act

No regulatory flexibility analysis (or certification that one is not required) is necessary because the rules are procedural,and thus not within the definition of "rule" for purposes of Chapter 6, Title 54, U.S.C.

List of Subjects in Part 200

Administrative practice and procedure, Freedom of information, Privacy, Securities.

Text of Amendments

PART 200—ORGANIZATION, CONDUCT AND ETHICS, AND INFORMATION AND REQUESTS

In consideration of the foregoing, the Commission hereby amends Part 200 of Chapter II, Title 17, Code of Federal Regulations as follows:

1. Paragraph (b)(6) of § 200.735–4 is revised as follows:

§ 200.735–4. Outside employment and activities.

* * * * *

(b) * * *

(6)(i) Subject to the specific prohibition and requirements set forth below, the Commission may accept payment or reimbursement in cash or in kind, for travel and subsistence expenses actually incurred by Commission members and employees, while on official duty status, in connection with the participation of such members and employees in conferences, proceedings, meetings, seminars, and educational programs concerning the functions and responsibilities of the Commission and related topics.

(ii)(A) The Commission shall accept no payment or reimbursement for expenses described in paragraph (b)(6)(i) of this section from or in connection with a conference sponsored by:

(*1*) A person directly required to file reports or registration statements with the Commission, or

(*2*) A person directly or indirectly regulated by the Commission, or

(*3*) Any association or other group composed predominantly of persons regulated by the Commission, *Provided, however,* That the Chairman may authorize the Commission to accept payment or reimbursement from such a group. In determining whether to authorize such payment or reimbursement, the Chairman shall consider the benefits to the Commission and the public of participation in the particular program and the possibility of any appearance of impropriety.

(B) For purposes of this section, the phrase "person regulated by the Commission" means all persons whose activities are directly regulated by, or who are required to register with, the Commission, including but not limited to, such persons as brokers or dealers in securities, national securities exchanges, national securities associations, investment companies, investment advisers, public utility holding companies, and any self-regulatory organization, as that term is defined in Section 3 of the Securities Exchange Act of 1934, 15 U.S.C. 78(c).

(iii)(A) Subordinate members of the staff who are invited to participate in programs which offer payment or reimbursement meeting the criteria of paragraph (b)(6)(i) of this section must, prior to participation, obtain the written approval of their Division Director, Office Head, or Regional Administrator to participate in the program and the written approval of the Chairman, if paragraph (b)(6)(ii)(A)(*3*) of this section applies. If paragraph (b)(6)(ii)(A)(*3*) of this section does not apply, the Executive Director shall determine in writing whether the Commission will accept the payment or reimbursement.

(*1*) In acting on requests to participate, Division Directors, Office Heads, and Regional Administrators shall consider: (*i*) the benefit to the Commission and the public of participation; (*ii*) the expertise of the proposed participant; and (*iii*) the appropriate allocation of resources.

(*2*) In determining whether the Commission shall accept payment or reimbursement, the Executive Director shall consider the possibility of any appearance of impropriety.

(B) Division Directors, Office Heads, and Regional Administrators must, prior to participation, obtain the written approval of the Chairman, if paragraph (b)(6)(ii)(A)(*3*) of this section applies. If paragraph (b)(6)(ii)(A)(*3*) of this section does not apply, the Executive Director shall determine, in writing, considering the possibility of any appearance of impropriety, whether the Commission will accept the payment or reimbursement. Division Directors, Office Heads, and Regional Administrators shall make the determinations specified in paragraph (b)(6)(iii)(A)(*1*) of this section as to their own participation.

(C) Except if paragraph (b)(6)(ii)(A)(*3*) of this section applies, each Commissioner shall determine for himself or herself whether payment or reimbursement for his or her expenses incident to participation in programs meeting the criteria of paragraph (b)(6)(i) of this section should be accepted by the Commission. Notice of each decision shall be sent to the Executive Director.

(D) Whenever it is determined, pursuant to paragraphs (b)(6)(iii)(A), (B), or (C) of this section that the Commission will accept a particular payment or reimbursement, the Executive Director shall forward notice of that decision to the Public Reference Room, Washington, D.C., for insertion in a public file.

(iv) Payment or reimbursement shall not be accepted for expenses which are unreasonable or lavish.

(v) On a quarterly basis, the Commission shall publish in the *SEC Docket* a compilation of payments and reimbursements accepted.

(vi) The Commission's acceptance from any person of payment or reimbursement for the expenses of a spouse or traveling companion accompanying a member or employee is prohibited. If a staff member wishes to participate in a program which offers payment or reimbursement meeting the criteria of paragraph (b)(6)(i) of this section and acceptance would not be prohibited by paragraph (b)(6)(ii) of this section, but is denied approval in accordance with paragraphs (b)(6)(iii)(A) or (B) of this section, or wishes to accept reimbursement for the travel expenses of his or her spouse or traveling companion, the staff member may participate in the program and accept such reimbursement personally, *Provided,* That:

(A) No reimbursement for travel expenses may be accepted from a person who does, or is seeking to do, business with the Commission, is

regulated directly or indirectly by the Commission, is registered with the Commission, or has interests which may be substantially affected by the official's performance or non-performance of his or her official duties.

(B) No reimbursement may be accepted for the travel expenses of an employee's spouse or traveling companion unless the prior written approval of the General Counsel is obtained. Under appropriate circumstances, such as programs where participants are expected to engage in social activities, the General Counsel may approve acceptance upon written application.

(C) A copy of the General Counsel's approval and notice of the amount of payment or reimbursement accepted from the sponsor must be sent to the Executive Director for inclusion in the public file in accordance with paragraph (b)(6)(iii)(D) of this section.

(D) Such staff member's participation and travel occur only while on annual leave, approved in accord with regular leave procedures. *Note* 7 CFR 200.735–4(e)(2)(ii).

* * * * *

The Commission finds that the foregoing action relates solely to rules of agency procedure or practice and, accordingly, that notice and prior publication for comments under the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*, are unnecessary. *See* 5 U.S.C. 553(b).

By the Commission.

George A. Fitzsimmons,

Secretary.

August 23, 1983.

[FR Doc. 83-23833 Filed 8-29-83; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket No. 83C-0128]

Color Additives; D&C Yellow No. 10

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is "permanently" listing D&C Yellow No. 10 for use in drugs and cosmetics, except for use in the area of the eye. This action is in response to a petition filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, Inc.), the Pharmaceutical Manufacturers Association, and the Certified Color Industry Committee (now the Certified Color Manufacturers Association). This rule will remove D&C Yellow No. 10 from the provisional list of color additives for use in drugs and cosmetics. Published elsewhere in this issue of the **Federal Register** is an order extending the closing date for the provisional listing of D&C Yellow No. 10 until November 1, 1983, to provide an opportunity for the filing of objections to this order.

DATES: Effective September 30, 1983, objections by September 29, 1983.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 1968 (33 FR 17205), FDA announced that a petition (CAP 8C0062) for the permanent listing of D&C Yellow No. 10 as a color additive for use in drugs and cosmetics, except for use in the area of the eye, had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, Inc.), the Pharmaceutical Manufacturers Association, and the Certified Color Industry Committee (now the Certified Color Manufacturers Association), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046 (now 9200 Leesburg Turnpike, Vienna, VA 22180).

The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376). A later notice in the **Federal Register** of March 5, 1976 (41 FR 9584), amended the notice of filing of the petition to include the use of D&C Yellow No. 10 in cosmetics intended for use in the area of the eye.

I. Toxicological Testing of D&C Yellow No. 10

In the **Federal Register** of September 23, 1976 (41 FR 41860), FDA stated that it no longer considered existing toxicological studies to be adequate to support the continued provisional listing of several color additives, including D&C Yellow No. 10. The agency explained that the studies were deficient in the following respects (41 FR 41863):

1. Many of the studies were conducted using groups of animals, i.e., control and those fed the color additive, that were too small to permit conclusions to be drawn today on the chronic toxicity or carcinogenic potential of the color additives tested. The small number of animals used does not, in and of itself, cause this result but when considered together with the other deficiencies in this listing, does do so. By and large, the studies used 25 animals in each group; today FDA recommends using at least 50 animals per group.

2. In a number of the studies, the number of animals surviving to a meaningful age was inadequate to permit conclusions to be drawn today on the chronic toxicity or carcinogenic potential of the color additives tested.

3. In a number of the studies, an insufficient number of animals was reviewed histologically.

4. In a number of the studies, an insufficient number of tissues was examined in those animals selected for pathology.

5. In a number of the studies, lesions or tumors detected under gross examination were not examined microscopically.

The agency proposed that the continued provisional listing of these color additives, including D&C Yellow No. 10, for use in ingested drugs and cosmetics be conditioned upon at least one petitioner undertaking new chronic feeding studies for each of these color additives. The agency did not require any additional studies for the continued provisional listing of D&C Yellow No. 10 for use in externally applied drugs and cosmetics.

FDA intended that the new chronic studies on the use of D&C Yellow No. 10 in ingested drugs and cosmetics would provide important evidence upon which to determine whether to list this color additive. Additionally, the agency noted that these studies would serve to replace the generally antiquated and deficient studies that supported the provisional listing regulations then in effect for the color additive.

When the petitioners agreed to sponsor the required chronic toxicity studies of the color additive, FDA postponed the closing date for the provisional listing of D&C Yellow No. 10 to January 31, 1981, in a notice published in the **Federal Register** of February 4, 1977 (42 FR 6992).

In the **Federal Register** of August 21, 1979 (44 FR 48964), FDA established temporary tolerances for the use of D&C Yellow No. 10 in ingested drugs and cosmetics. These temporary tolerances were adopted to assure that use of the color additive would not exceed a safe level of exposure. They were based on usage information and data from chronic animal feeding studies, submitted by the petitioners, in which no adverse effects

were noted at the highest dose tested. FDA received an objection in response to this order requesting that the use of D&C Yellow No. 10 be limited only by good manufacturing practice. The agency considered this objection and concluded that the limits prescribed by the order on the use of this color additive were necessary to protect the public health (April 4, 1980; 45 FR 22904).

FDA established a closing date of April 30, 1983, for the provisional listing of D&C Yellow No. 10 in the **Federal Register** of March 27, 1981 (46 FR 18954). The agency subsequently established the closing date of July 1, 1983, for the provisional listing of D&C Yellow No. 10 in a rule published in the **Federal Register** of April 29, 1983 (48 FR 19366). FDA's review and evaluation of the data relevant to the use of D&C Yellow No. 10 required more time than anticipated, however. The agency therefore extended the closing date to September 2, 1983, in the **Federal Register** of July 1, 1983 (48 FR 30357), to provide time to complete its review and prepare this document. Published elsewhere in this issue of the **Federal Register** is an order extending the closing date for the provisional listing of D&C Yellow No. 10 until November 1, 1983, to provide an opportunity for the filing of objections to this order.

II. Analysis of Data

The agency has completed its evaluation of the color additive petition for D&C Yellow No. 10, including the new chronic toxicity studies in rats and mice. The agency previously reviewed reports on a number of other toxicity studies, involving rats and dogs, of D&C Yellow No. 10. These studies included acute oral toxicity studies, 3-month feeding studies, and 2-year feeding studies. These studies did not produce any evidence that the use of this color additive would be unsafe for the petitioned uses. The agency concluded, however, that the additional chronic toxicity feeding studies were required to provide data to permit a final determination to be made on the listing of D&C Yellow No. 10 (41 FR 41860; September 23, 1976).

The new chronic studies in rats and mice represent current state-of-the-art toxicological testing. The protocols for these studies have benefited from knowledge of deficiencies in previously conducted carcinogenesis bioassays and other chronic toxicity studies. The use of large numbers of animals of both sexes, pilot studies to determine maximum tolerated dosages, two control groups (thereby effectively doubling the number of controls), and in utero exposure in one of the two species tested (the rat) significantly increase the power of these tests for detecting dose-related effects. The studies were designed and conducted in full compliance with the current good laboratory practice reglations and were subject to FDA inspection while the studies were conducted.

The chronic feeding study in male and female Charles River CD Sprague Dawley rats actually consisted of two studies of the same design. In the first study, the animals were fed 0.03, 0.10, and 0.5 percent D&C Yellow No. 10 in the diet. The animals in the second study received higher concentrations (2.0 and 5.0 percent) of the color additive in the diet. No effects on tumor incidence, survival, food consumption, clinical observations, or pathological findings were observed that were attributable to the ingestion of D&C Yellow No. 10. The results of the first study showed that mean body weights for the treated males and females were comparable to the control body weights throughout the study. In the second study, body weights of male rats that were fed diets containing 5.0 percent D&C Yellow No. 10 were less than the controls throughout the study ($P < 0.05$). Male and female animals fed 2.0 percent D&C Yellow No. 10 did not demonstrate a significant decrease in body weight over the course of the study.

In the chronic feeding study with Charles River CD–1 mice of both sexes, the animals were fed 0.10, 1.0, and 5.0 percent D&C Yellow No. 10 in the diet. Sporadic occurrences of reduced body weights were observed in treated male animals, but the findings were not statistically significant or dose-related. There was no increased incidence of tumors that could be attributed to the ingestion of D&C Yellow No. 10.

Based on its evaluation of the results of the two new chronic toxicity studies, the agency has determined that D&C Yellow No. 10 is not carcinogenic to Charles River CD Sprague Dawley rats or Charles River CD–1 mice after a lifetime dietary exposure of up to 5.0 percent of the color additive for each species. Based on the occurrence of reduced body weights in rats fed 5 percent D&C Yellow No. 10, the agency has established a "no effect" level at 2 percent in rats. Using an appropriate safety factor (see 21 CFR 70.40), the agency has estimated a maximum acceptable daily intake for humans of aproximately 10 milligrams per kilogram of body weight per day (600 milligrams per day for a 60-kilogram person).

The agency has also completed its evaluation of the other animal studies submitted by the petitioner for the purpose of establishing the safety of D&C Yellow No. 10 for use in externally applied drugs and externally applied cosmetics. Dermal studies intended to support the safety of external uses of D&C Yellow No. 10 were conducted with D&C Yellow No. 11, the oil soluble (nonsulfonated) dye used to manufacture D&C Yellow No. 10. The agency considered the use of D&C Yellow No. 11 as representative in dermal studies for the water soluble D&C Yellow No. 10 because D&C Yellow No. 11 is similar in structure to D&C Yellow No. 10 and expected to have greater skin penetration. Thus, the agency concluded that these dermal studies can appropriately be used in evaluating the safety of D&C Yellow No. 10. The dermal studies included skin irritation and percutaneous toxicity studies in albino rabbits and a lifetime skin painting study for carcinogenesis in Swiss-Webster mice. With respect to dermal safety, the studies on D&C Yellow No. 11 indicate that the closely related D&C Yellow No. 10 is nonirritating to the skin and is not systemically toxic through percutaneous absorption. Furthermore, D&C Yellow No. 11 was not found to be carcinogenic when applied to the skin of mice. Therefore, FDA can conclude to a reasonable certainty that no harm will result from the petitioned dermal uses of D&C Yellow No. 10.

III. Identity and Method of Manufacture

D&C Yellow No. 10 (21 CFR 82.1710) originally was listed as the disodium salt of disulfonic acid of 2-(2-quinolinyl)-1,3-indandione. The agency has since determined that the color additive that was toxicologically tested in the chronic animal feeding studies discussed above and certified as D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione, consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid, with lesser amounts of disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione. Therefore, the agency concludes that D&C Yellow No. 10 is appropriately identified as a mixture of mono- and disulfonated sodium salts, principally in the monosulfonated form.

The agency also concludes that it is necessary to include in the listing regulation for D&C Yellow No. 10 a brief description of its manufacturing process to ensure the safety of this color additive. The agency is concerned that

D&C Yellow No. 10 may contain potentially toxic impurities dependent upon the manufacturing process used to produce it.

In the manufacture of D&C Yellow No. 10, one of the starting materials, 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (D&C Yellow No. 11), may remain in the color additive as a minor impurity. D&C Yellow No. 11 is permanently listed for use only in externally applied drugs and cosmetics because the available toxicological studies failed to establish a safe level for ingested use. Adverse effects were found in the livers of rats and dogs fed D&C Yellow No. 11 in short-term and chronic studies. Analysis of batches of D&C Yellow No. 10 used in the recent toxicity tests showed the presence of almost 2 parts per million (ppm) of D&C Yellow No. 11 and 1 ppm of other diethyl ether soluble matter, which is mostly chlorinated D&C Yellow No. 11. Although no hepatotoxic effects were observed in animals exposed to the D&C Yellow No. 10 toxicology sample, FDA believes that in the interest of safety it is necessary to set limits for D&C Yellow No. 11 and its chlorinated derivative in D&C Yellow No. 10 because of the adverse effects found in the D&C Yellow No. 11 studies. These limits will ensure that future batches of D&C Yellow No. 10 are consistent with the batches used in the toxicological testing. The agency is setting a specification for D&C Yellow No. 11 of 4 ppm and for the other diethyl ether soluble matter of 2 ppm. FDA expects that, on the average, the levels of these minor constituents in batches of D&C Yellow No. 10 certified under the specifications will be below the levels set in the specifications and consistent with the toxicological sample. To further characterize batches of D&C Yellow No. 10 for certification, the agency is also setting specifications for other impurities that have been detected in certification samples of D&C Yellow No. 10.

The agency, however, is not able at this time to set specifications that would control the presence of all impurities in D&C Yellow No. 10. The agency has contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to develop appropriate specifications for color additives for use in food as part of the Food Chemicals Codex. Similarly, appropriate specifications for color additives for use in drugs and cosmetics will be developed following the general guidelines used by NAS/NRC in its evaluation of color additives used in food. The agency concludes that specifying, through a general description, the manufacturing process in the regulations for these color additives will provide an adequate assurance of safety until suitable specifications can be developed. Production of the color additive by the specified method will assure qualitatively similar batches and thus adequately assure the absence of harmful impurities resulting from changes in the manufacturing process.

The agency is including a description of the manufacturing procedure in 21 CFR 74.1710(a) and is incorporating it by reference in 21 CFR 74.2710(a) for cosmetics.

IV. Conclusions

The agency concludes that D&C Yellow No. 10 is safe under the conditions of use set forth below for use in drugs and cosmetics, and that certification is necessary for the protection of the public health. The final chronic toxicity study reports, interim reports, and the agency's toxicology evaluations of these studies are on file at the Dockets Management Branch (address above). They may be reviewed there between 9 a.m. and 4 p.m., Monday through Friday.

V. Eye-Area Use

FDA notified the petitioners by letters dated June 21, 1974, January 29, 1976, February 5, 1976, and August 15, 1977, of the need for data to support the use of D&C Yellow No. 10 in cosmetics intended for use in the area of the eye. In a fifth letter, dated October 24, 1978, FDA advised the petitioners to consider withdrawing that portion of the petition that sought approval of the use of D&C Yellow No. 10 in cosmetics intended for use in the area of the eye because the required data from eye-area studies apparently were not readily available.

The petitioners have not submitted the required data for eye-area use. Therefore, FDA now considers that portion of the petition that was amended by the filing on March 5, 1976 (Docket No. 76C-0043) to include the permanent listing of D&C Yellow No. 10 for eye-area use to be withdrawn without prejudice in accordance with the provisions of § 71.4 (21 CFR 71.4). Section 71.4 requires that such information be submitted within 180 days after filing of the petition, or the petition will be considered withdrawn without prejudice.

Use of D&C Yellow No. 10 in the area of the eye has never been covered by provisional listing. Future consideration by FDA of the permanent listing of D&C Yellow No. 10 for eye-area use will require the submission of a new color additive petition for that use. The agency's listing of a color additive for use in drugs and cosmetics does not encompass eye-area use.

The agency has determined pursuant to 21 CFR 25.24(b)(12) and (d)(5) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 74

Color additives, Color additives subject to certification, Cosmetics, Drugs.

21 CFR Part 81

Color additives, Color additives provisional list, Cosmetics, Drugs.

21 CFR Part 82

Color additives, Color additives lakes, Color additives provisional list, Cosmetics, Drugs.

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 under 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 of Food and Drugs (21 CFR 5.10), Parts 74, 81, and 82 are amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By adding new § 74.1710 to read as follows:

§ 74.1710 D&C Yellow No. 10.

(a) *Identity.* (1) The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004-92-0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

(2) Color additive mixtures made with D&C Yellow No. 10 for drug use may

contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Yellow No. 10 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 current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in both water and chloroform, not more than 0.2 percent.
Total sulfonated quinaldines, sodium salts, not more than 0.2 percent.
Total sulfonated phthalic acids, sodium salts, not more than 0.2 percent.
2-(2-Quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 4 parts per million.
Sum of sodium salts of the monosulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not less than 75 percent.
Sum of sodium salts of the disulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 15 percent.
2-(2,3-Dihydro-1,3-dioxo-1*H*-indene-2-yl)-6, 8-quinolinedisulfonic acid, disodium salt, not more than 3 percent.
Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.
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.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts not to exceed 10 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.2710 to read as follows:

§ 74.2710 D&C Yellow No. 10.

(a) *Identity and specifications.* The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics in amounts consistent with current good manufacturing practice. D&C Yellow No. 10 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 1.0 percent by weight of the finished lipstick or other cosmetic.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOOD, DRUGS, AND COSMETICS

2. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* by removing the entry for "D&C Yellow No. 10" from the table in paragraph (b).

§ 81.25 [Amended]

b. In § 81.25 *Temporary tolerances* by removing the entries for "D&C Yellow No. 10" from paragraphs (a)(1), (b)(1)(i), and (c)(1).

§ 81.27 [Amended]

c. In § 81.27 *Conditions of provisional listing* by removing the entry for "D&C Yellow No. 10" from the table in paragraph (d).

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended by revising § 82.1710, to read as follows:

§ 82.1710 D&C Yellow No. 10.

The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b) of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 28, 1983 file with the Dockets Management Branch (address above) written objections thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing and 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. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective September 30, 1983, 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(d), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: August 25, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-23708 Filed 8-29-83; 8:45 am]

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21 CFR Part 81

[Docket No. 76N-036E]

Provisional Listing of D&C Yellow No. 10 for Use in Drugs and Cosmetics; Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Yellow No. 10 for use as a color additive in drugs and cosmetics. The new closing date will be November 1, 1983. This brief postponement will provide time for the receipt and evaluation of any objections submitted in response to the final rule (published elsewhere in this issue of the **Federal Register,**) approving the petition for the listing of D&C Yellow No. 10 for these uses.

DATES: Effective September 2, 1983, the new closing date for D&C Yellow No. 10 will be November 1, 1983.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of September 2, 1983, for the provisional listing of D&C Yellow No. 10 for use in drugs and cosmetics by a rule published