excluded from the tight formation designation. The excluded area consisted of only those 320-acre drilling units which were developed prior to the issuance of Colorado Order No. 232–20.

On July 19, 1982, Colorado submitted a request that the final rule issued in Order No. 124 be corrected by amending the acreage designated as the Wattenberg J Sand Formation. Colorado submitted data to verify that ten 320-acre drilling units had been incorrectly included in the excluded area, determined to be developed prior to the date of Order No. 232–20, and asked that these areas now be included in the tight formation. Additionally, Colorado noted that two 320-acre drilling units which had been developed prior to the issuance of Order No. 232-20 were erroneously included in the area designated as a tight formation in Order No. 124, and asked that they now be excluded.

The amendment requested by Colorado was contained in a Notice of Proposed Rulemaking by the Director, Office of Pipeline and Producer Regulation, issued August 17, 1982 (47 FR 36434, August 20, 1982). One comment was received in response to the Notice of Proposed Rulemaking, which supported the amendment to the designation as recommended by Colorado.

The Notice specifically requested comments concerning whether any drilling activity was undertaken in reliance on Order No. 124, in the areas now recommended to be deleted. No comments on this issue were received, but the Commission staff has verified through Colorado that there has been no new drilling activity in the area to be deleted since the issuance of Order No. 124.

The Commission finds that the evidence submitted by Colorado supports its assertion that the Wattenberg J Sand Formation underlying the ten 320-acre units previously excluded from the tight formation designation in Order No. 124 satisfies the guidelines found in § 271.703(c) and should be added to the designation of the Wattenberg J Sand Formation as made in that order. Additionally, the Commission finds that the two areas which were included in the designation, in which Colorado now states development had occurred prior to the issuance of the infill drilling order, should be excluded from the Wattenberg J Sand tight formation designation. The Commission adopts the Colorado recommendation.

This amendment shall become effective November 22, 1982. The Commission has found that the public interest dictates that new natural gas supplies be developed on an expedited basis, and, therefore, incentive prices should be made available as soon as possible. The need to make incentive prices immediately available establishes good cause to waive the thirty-day publication period.

List of Subjects in 18 CFR Part 271

Natural gas, Incentive price, Tight formations.

(Department of Energy Organization Act, 42 U.S.C. 7101 *et seq.*; Natural Gas Policy Act of 1978, 15 U.S.C. 3301–3432; Administrative Procedure Act, 5 U.S.C. 553)

In consideration of the foregoing, Part 271 of Subchapter H, Chapter I, Title 18, Code of Federal Regulations, is amended as set forth below, effective November 22, 1982.

By the Commission.

Lois D. Cashell,

Acting Secretary.

PART 271—CEILING PRICES

§ 271.703 [Amended]

Section 271.703(d)(11) is amended in the appendix to Order No. 124, Docket No. RM79–76 (Colorado-1), by removing the following from the area excluded from the tight formation designation:

Weld County

Township 1 North, Range 66 West, 6th P.M., Section 20: W½
Township 2 North, Range 65 West, 6th P.M., Section 04: E½
Township 2 North, Range 67 West, 6th P.M., Section 16: W½ Section 20: N½
Township 2 North, Range 68 West, 6th P.M., Section 16: E½ Section 22: W½
Township 3 North, Range 65 West, 6th P.M., Section 12: E½ Section 32: W½
Township 3 North, Range 66 West, 6th P.M., Section 16: all.

By adding the following to the area excluded from the tight formation designation:

Weld County

Township 2 North, Range 68 West, 6th P.M., Section 16: W½
Township 3 North, Range 65 West, 6th P.M., Section 32: E½

[FR Doc. 82-32627 Filed 11-29-82; 8:45 am]
BILLING CODE 6717-01-M

18 CFR Part 282

[Docket No. RM79–14]

Natural Gas Policy Act of 1978; Order of the Director, OPPR of Publication of Incremental Pricing Acquisition Cost Thresholds Under Title II

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order prescribing incremental pricing thresholds.

SUMMARY: The Director of the Office of Pipeline and Producer Regulation is issuing the incremental pricing acquisition cost thresholds prescribed by Title II of the Natural Gas Policy Act and 18 CFR 282.304. The Act requires the Commission to compute and publish the threshold prices before the beginning of each month for which the figures apply. Any cost of natural gas above the applicable threshold is considered to be an incremental gas cost subject to incremental pricing surcharging.

EFFECTIVE DATE: December 1, 1982.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Williams, Federal Energy Regulatory Commission, 825 N. Capitol Street, N.E., Washington, D.C. 20426; (202) 357–8500.

SUPPLEMENTARY INFORMATION:

In the matter of publication of prescribed incremental pricing acquisition cost threshold of the NGPA of 1978, Docket No. RM 79–14.

Issued: November 23, 1982.

Section 203 of the NGPA requires that the Commission compute and make available incremental pricing acquisition cost threshold prices prescribed in Title II before the beginning of any month for which such figures apply.

Pursuant to that mandate and pursuant to § 375.307(l) of the Commission's regulations, delegating the publication of such prices to the Director of the Office of Pipeline and Producer Regulation, the incremental pricing acquisition cost threshold prices for the month of December 1982 is issued by the publication of a price table for the applicable month.

List of Subjects in 18 CFR Part 282

Natural gas.

Kenneth A. Williams,

Director, Office of Pipeline and Producer Regulation.

TABLE I.—INCREMENTAL PRICING ACQUISITION COST THRESHOLD PRICES

Calendar Year 1980

	January	February	March	April	May	June	July	August	September	October	November	December
Incremental Pricing Threshold	$1.702	$1.738	$1.750	$1.762	$1.776	$1.790	$1.804	$1.819	$1.834	$1.849	$1.863	$1.877
NGPA Section 102 Threshold	2.358	2.381	2.404	2.428	2.453	2.478	2.504	2.532	2.560	2.588	2.614	2.640
NGPA Section 109 Threshold	1.786	1.799	1.812	1.825	1.839	1.853	1.867	1.883	1.899	1.915	1.929	1.934
130% of No. 2 Fuel Oil in New York City Threshold	7.170	7.260	7.410	7.110	7.380	8.040	7.840	7.380	7.400	7.400	7.450	7.580

Calendar Year 1981

Incremental Pricing Threshold	$1.891	$1.908	$1.925	$1.942	$1.954	$1.967	$1.980	$1.990	$2.000	$2.010	$2.025	$2.041
NGPA Section 102 Threshold	2.667	2.698	2.729	2.761	2.787	2.813	2.840	2.863	2.886	2.909	2.940	2.971
NGPA Section 109 Threshold	1.957	1.975	1.993	2.011	2.024	2.037	2.050	2.060	2.070	2.080	2.096	2.112
130% of No. 2 Fuel Oil in New York City Threshold	7.610	7.760	8.260	9.010	9.510	9.430	9.360	9.260	8.860	8.700	8.930	8.990

Calendar Year 1982

Incremental Pricing Threshold	$2.057	$2.071	$2.085	$2.099	$2.106	$2.113	$2.120	$2.129	$2.139	$2.149	$2.159	$2.169
NGPA Section 102 Threshold	3.003	3.033	3.063	3.093	3.112	3.132	3.152	3.176	3.200	3.224	3.249	3.274
NGPA Section 109 Threshold	2.128	2.143	2.158	2.173	2.180	2.187	2.194	2.204	2.214	2.224	2.234	2.244
130% of No. 2 Fuel Oil in New York City Threshold	9.180	9.340	9.470	9.340	9.280	8.000	8.170	8.670	8.660	8.950	8.640	8.890

[FR Doc. 82-32626 Filed 11-29-82; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket No. 82N-0341]

D&C Red No. 21 and D&C Red No. 22

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is permanently listing D&C Red No. 21 and D&C Red No. 22 for general use in drugs and cosmetics excluding use in the area of the eye. This action is in response to a petition filed by the Cosmetic, Toiletry and Fragrance Association, Inc. This rule will remove D&C Red No. 21 and D&C Red No. 22 from the provisional list of color additives for general use in drugs and cosmetics. To provide an opportunity for objections, published elsewhere in this issue of the **Federal Register** is an order extending the closing date for the provisional listing of D&C Red No. 21 and D&C Red No. 22 until March 1, 1983.

DATES: Effective January 3, 1983; objections by December 30, 1982.

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: John L. Herrman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1973 (38 FR 21199), FDA announced that a petition (CAP 6C0043) for the permanent listing of D&C Red No. 21 and D&C Red No. 22 as color additives for general use in drugs and cosmetics had been filed by the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), 1110 Vermont Ave. NW., Washington, DC 20005. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

Toxicological Testing of D&C Red No. 21 and D&C Red No. 22

The provisional regulations published in the **Federal Register** of February 4, 1977 (42 FR 6992), required new chronic toxicity studies for D&C Red No. 21 and D&C Red No. 22 as a condition of their continued provisional listing for ingested uses. FDA placed these requirements on 31 color additives because the toxicity studies that the peititioners had submitted to support the safe use of these color additives were deficient in several respects. FDA described these deficiencies in the **Federal Register** of September 23, 1976 (41 FR 41863):

1. Many of the studies were conducted using groups of animals, i.e., control and those fed the color additive, that are too small to permit conclusions to be drawn today on the chronic toxicity or carcinogenic potential of the color. 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.

FDA postponed the closing date for the provisional listing of the color additives until January 31, 1981, for the completion of the required chronic toxicity studies. FDA later extended the closing date for completing these studies and submitting data. In a proposal in the **Federal Register** of November 14, 1980 (45 FR 75226), the agency outlined the reasons for postponing the closing dates for 23 provisonally listed color additives under test, including D&C Red No. 21 and D&C Red No. 22, beyond January 31, 1981.

In the **Federal Register** of March 27, 1981 (46 FR 18958), the agency established a new closing date of November 30, 1982 for the complete evaluation of D&C Red No. 21 and D&C Red No. 22. When the order set forth below becomes effective it will remove D&C Red No. 21 and D&C Red No. 22 from the provisional list. Published elsewhere in this issue of the **Federal Register** is an order that extends the closing date for the provisional listing of D&C Red Nos. 21 and 22 until March 1, 1983, to provide an opportunity for filing objections to this order.

Evaluation of the Safety of D&C Red No. 21 and D&C Red No. 22 for Drug and Cosmetic Use

The agency has completed its evaluation of the color additive petition for D&C Red No. 21 and D&C Red No. 22, including two new chronic toxicity studies in rats and mice.

The test material in all of the toxicity studies was D&C Red No. 21. Because D&C Red No. 22 is the disodium salt of D&C Red No. 21, the agency considers the two color additives to be toxicologically equivalent. Thus any safety conclusion drawn from studies of D&C Red No. 21 applies equally to D&C Red No. 22.

The agency previously reviewed reports on a number of other animal toxicity studies on D&C Red No. 21. These included acute oral toxicity studies in rats and dogs, an 18-week feeding study in rates, 2-year feeding studies in rats and dogs, a dermal study with rabbits, an 18-month skin painting study with mice, a metabolism and excretion study in rats, a 3-generation reproduction study in rats, and teratology studies in rats and rabbits. These studies did not produce any evidence that the use of this color additive, for the petitioned uses, would be unsafe. The agency concluded, however, that new chronic toxicity feeding studies would be required to provide data to permit a final determination to be made on the listing of D&C Red Nos. 21 and 22 (41 FR 41860; September 23, 1976).

The new long-term chronic studies 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 protocols. 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 two species tested significantly increases the power of these tests to detect dose-related effects. The studies were designed and conducted in full compliance with the FDA's good laboratory practice regulations and were subject to inspections by FDA officials during their course.

In the new chronic feeding study with male and female CD–1 mice, animals were fed diets containing D&C Red No. 21 at concentrations of 0.125, 0.50, and 1.0 percent of their diets. The petitioner reported that the incidence of hepatocellular carcinoma among male mice in the treated groups was higher than that in the study controls, but that this finding was not toxicologically significant because the incidence among control animals was unusually low, and because the incidence in treated animals was well within the expected incidence for this species and strain. To clarify this issue, however, by letter dated May 28, 1982, FDA requested, among other things, that microslides be prepared from tissue sections taken from the livers of all male mice in the mid- and low-dosage groups, and that these microslides, together with all microslides of the livers of male mice previously sectioned, be submitted by the petitioner for pathology review. FDA also requested historical control data on the incidence of hepatocellular neoplasms at the testing laboratory.

On July 2, 1982, and July 26, 1982, CTFA submitted to FDA the requested information. The petitioner included in these submissions (1) microslides from tissue sections of the livers of all male mice from the two control groups and the three groups fed diets containing D&C Red No. 21 and (2) historical data on the incidence of hepatocellular carcinomas and hepatocellular adenomas in CD–1 mice serving as controls at the testing laboratory.

FDA pathologists initially examined all the slides without knowing the identity of the experimental group to which the slide being examined belonged. The FDA diagnoses were made by a consensus of three pathologists within the Bureau of Foods. The FDA diagnoses showed two fewer animals with hepatocellular carcinomas in the control groups, three fewer animals with hepatocellular carcinomas in the mid-dose group, and four fewer animals with hepatocellular carcinomas in the high-dose group than reported by the testing laboratory. The FDA diagnoses of all the slides showed the incidence of hepatocellular carcinoma to be 1/118 (0.8 percent) in the control groups, 6/59 (10.2 percent) in the low-dose group, 4/60 (6.7 percent) in the mid-dose group, and 6/60 (10 percent) in the high-dose group. The incidence of hepatocellular carcinoma in the control groups is substantially below the historical incidence of hepatocellular carcinoma in control groups at the testing laboratory, which averaged 8.6 percent and which ranged from 4.0 to 18.3 percent in the same strain of mouse in five studies performed within approximately three years of the D&C Red No. 21 study. The incidences in all three treated groups are well within the range of this historical control incidence.[1] This fact, coupled with the lack of a dose-response relationship among the treated groups, leads FDA to conclude that there is no relationship between the occurrence of hepatocellular carcinoma in male mice and treatment with D&C Red No. 21.

More importantly, for a number of reasons, including the difficulty of distinguishing tumor types, FDA believes that in analyzing the data, hepatocellular carcinomas and adenomas should be combined for statistical analysis. Considering both types of tumors together, the FDA diagnoses showed one more animal with hepatocellular neoplasm in the control groups, four fewer animals with hepatocellular neoplasms in the mid-dose group, and two fewer animals with hepatocellular neoplasms in the high-dose group than reported by the contracting laboratory. The FDA diagnoses of all the slides showed the combined incidence of hepatocellular adenomas and carcinomas to be 14/118 (11.9 percent) in the control groups, 10/59 (16.9 percent) in the low-dose group, 9/60 (15.0 percent) in the mid-dose group, and 14/60 (23.3 percent) in the high-dose group. The time-adjusted prevalence analyses for the comparison of the high-dose group to the combined control group and for the trend for these incidences gave p-values of 0.063 and 0.074 to 0.086 (depending upon continuity correction), respectively. The agency considers that these values do not support a treatment-related effect. Furthermore, the combined incidences of hepatocellular carcinomas and adenomas in each of the treatment groups are well within the range of the historical control incidence of the testing laboratory for the same strain of mouse in five studies performed within approximately three years of the D&C Red No. 21 study. The agency also noted no relationship between occurrence of pre-neoplastic liver lesions and treatment with D&C Red No. 21. These considerations and the agency's review of all other data in the petition, including the fact that there was no treatment-related increase in incidence of any type of neoplasm in female mice, have led FDA to conclude that there is no indication of an association between the occurrence of neoplasms and the

[1] The use of appropriate historical data as an aid in evaluating data on a given chemical is a well-established practice. See, e.g., "Long-term and Short-term Screening Assays for Carcinogens: A Critical Appraisal," IARC Monographs, Supplement 2, World Health Organization, 1980, pp. 72 and 73 and Gart, J. J., Chu, K. C., and Tarone, R. E., *Journal of the National Cancer Institute*, 62:957–974, 1979.

administration of D&C Red No. 21 to mice.

In the new chronic feeding study with male and female Charles River CD rats, parental animals were fed diets containing D&C Red No. 21, at concentrations of 0.25, 1.0, or 2.0 percent, continuously from before mating until weaning of their offspring. The offspring were fed diets containing these same concentrations of D&C Red No. 21 for more than 30 months. The agency found no increases in incidence of tumors in any of the treated groups that could be attributed to exposure to this color additive.

Although there was no increase in the incidence of tumors in the new rat chronic feeding study, the agency noted that a variety of non-specific, non-neoplastic microscopic changes occurred in high dose-treated rats at incidences that were greater than in the combined control groups. The differences between control and high-dose groups were less than 10 percent. The incidence of some of these changes in the high-dose group was significantly increased when compared with their incidence in the control groups (Fisher's exact test, $p=0.0065$ to 0.0203). The agency therefore regards the high dose (2.0 percent) as an effect level. Because the increase in incidence in the high-dose group was so small, the agency concludes that these changes would not be observed at lower doses. Therefore, the agency has chosen the intermediate dose of 1.0 percent in the diet, corresponding to 500 milligrams per kilogram per day, as the no-adverse effect level. In the absence of more serious toxic effects in other tests, this rat study was used as the basis for calculating the acceptable daily intake (ADI). The ADI for humans was calculated by applying a 100-fold safety factor to the no-adverse effect level (see 21 CFR 70.40). This calculation yields a value of 5 milligrams per kilogram per day or 300 milligrams per day for a 60 kilogram person. Based on its review of available data on the current uses of D&C Red Nos. 21 and 22, FDA estimates that the upper limit lifetime-averaged internal exposure to these color additives from drugs and cosmetics is 6.3 milligrams per day (drugs, 5 milligrams and cosmetics, 1.3 milligrams). Thus, the acceptable daily intake of D&C Red Nos. 21 and 22 is approximately 47 times the estimated daily intake of the color additives.

Based upon its evaluation of the results of the two recently submitted chronic toxicity studies, the agency has determined that D&C Red No. 21 and D&C Red No. 22 are not carcinogenic to Charles River Sprague-Dawley CD rats or CD–1 mice after dietary exposure as high as 2.0 percent and 1.0 percent, respectively, under conditions of testing adequate to provide assurance for their safe use. The agency has also completed its evaluation of other animal studies submitted by the petitioner for the purpose of establishing the safety of D&C Red Nos. 21 and 22 for use in externally applied drugs and externally applied cosmetics. The data from these studies demonstrate that, with respect to dermal safety, D&C Red No. 21 is nonirritating when applied daily to either intact or abraded skin. Furthermore, D&C Red No. 21 was not found to be carcinogenic when applied twice weekly to the skin of mice over their lifetimes. Therefore, FDA finds that it can conclude to a reasonable certainty that no harm will result from the petitioned uses of D&C Red No. 21 and D&C Red No. 22.

Conclusion

The agency concludes that D&C Red No. 21 and D&C Red No. 22 are safe for general use in drugs and cosmetics excluding use in the area of the eye (see § 70.5 *General restrictions on color additives* (21 CFR 70.5)), and that certification is necessary for the protection of the public health. The final toxicity study reports, interim reports, and the agency's toxicology evaluations of these studies are on file at the Dockets Management Branch (address above) and may be reviewed there between 9 a.m. and 4 p.m., Monday through Friday.

The agency is establishing new chemical specifications that identify the color additives more precisely than those specifications currently in Part 82. The agency concludes that it is necessary to include in the listing regulations for D&C Red Nos. 21 and 22 a brief description of their manufacturing processes to ensure the safety of the color additives. The agency is concerned that the color additives may contain potentially toxic impurities dependent upon the manufacturing processes used to produce the color additives. The agency is not able at this time to set specifications that would control the presence of these impurities. 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 the 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 additives by the specified methods will assure qualitatively similar batches and thus adequately assure the absence of unanticipated potentially toxic impurities. Also, the chemical names for the two color additives in the new listings under 21 CFR Part 74 are different from the names currently listed under 21 CFR Part 82 and from the Chemical Abstracts designations. The agency has decided to follow the nomenclature commonly used in the chemical literature where these color additives are referred to as fluorescein derivatives.

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 lake, 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 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 § 74.1321 to Subpart B to read as follows:

§ 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086–94–9), and may contain smaller amounts of 2',4',5'-tribromofluorescein (CAS Reg. No. 25709–83–5) and 2',4',7'—tribromofluorescein (CAS Reg. No. 25709–84–6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 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 Red No. 21 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 current good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
Brominated resorcinol, not more than 0.4 percent.
Fluorescein, not more than 0.2 percent.
Sum of mono- and dibromofluoresceins, not more than 2 percent.
Tribromofluoresceins, not more than 11 percent.
2',4',5',7'-Tetrabromofluorescein, not less than 87 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.* The color additive D&C Red No. 21 may be safely used for coloring drugs generally in amounts consistent with current 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 § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.1322 to Subpart B to read as follows:

§ 74.1322 D&C Red No. 22.

(a) *Identity.* (1) The color additive D&C Red No. 22 is principally the disodium salt of 2',4',5'7'-tetrabromofluorescein (CAS Reg. No. 17372–87–1) and may contain smaller amounts of the disodium salts of 2',4',5'-tribomofluorescein and 2',4',7'-tribromofluorescein. The color additive is manufactured by alkaline hydrolysis of 2',4',5',7'-tetrabromofluorescein. 2',4',5',7'-Tetrabromofluorescein is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. Fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with Red No. 22 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 Red No. 22 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 current good manufacturing practice:

Sum of volatile matter (at 135°C) and halides and sulfates (calculated as soduim salts), not more than 10 percent.
Water-insoluble matter not more than 0.5 percent.
Disodium salt of phthalic acid, not more than 1 percent.
Sodium salt of 2-(3,5-Dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.5 percent.
2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
Brominated resorcinol, not more than 0.4 percent.
Sum of disodium salts of mono- and dibromofluoresceins, not more than 2 percent.
Sum of disodium salts of tribromofluoresceins, not more than 25 percent.
Disodium salt of 2',4',5',7'-Tetrabromofluorescein, not less than 72 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.* The color additive D&C Red No. 22 may be safely used for coloring drugs generally in amounts consistent with current 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 § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 22 shall be certified in accordance with regulations in Part 80 of this chapter.

c. By adding new § 74.2321 to Subpart C to read as follows:

§ 74.2321 D&C Red No. 21.

(a) *Identity and specifications.* The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

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

(d) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in Part 80 of this chapter.

d. By adding new § 74.2322 to Subpart C to read as follows:

§ 74.2322 D&C Red No. 22.

(a) *Identity and specifications.* The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 22 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

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

(d) *Certification.* All batches of D&C Red No. 22 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 FOODS, DRUGS, AND COSMETICS

2. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* by removing the entries for "D&C Red No. 21" and "D&C Red No. 22" from the table in paragraph (b).

§ 81.27 [Amended]

b. In § 81.27 *Conditions of provisional listing* by removing the entries for "D&C Red No. 21" and "D&C Red No. 22" from the table in paragraph (d).

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended:

a. By revising § 82.1321 to read as follows:

§ 82.1321 D&C Red No. 21.

The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321 (a)(1) and (b) of this chapter.

b. By revising § 82.1322 to read as follows:

§ 82.1322 D&C Red No. 22.

The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322 (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 December 30, 1982, file with the Dockets Management Branch (address above) written objections thereto. Objections shall show wherein 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 issues 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 January 3, 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 (b), (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 November 23, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-32729 Filed 11-26-82; 11:01 am]

BILLING CODE 4160-01-M

---

21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Red No. 21 and D&C Red No. 22; 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 Red No. 21 and D&C Red No. 22 for use as a color additive in drugs and cosmetics. The new closing date will be March 1, 1983. This brief postponement will provide time for the receipt and evaluation of any objections submitted in response to the final regulation (published elsewhere in this issue of the **Federal Register**) approving the petition for the listing of D&C Red No. 21 and D&C Red No. 22 for these uses.

DATES: Effective November 29, 1982, the new closing date for D&C Red No. 21 and D&C Red No. 22 will be March 1, 1983.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of November 30, 1982, for the provisional listing of D&C Red No. 21 and D&C Red No. 22 by a rule published in the **Federal Register** of March 27, 1981 (46 FR 18958). The agency extended the closing date until November 30, 1982, to provide time for the completion of chronic toxicity studies and the review and evaluation of these studies by FDA.

After reviewing and evaluating the data, the agency has concluded that D&C Red No. 21 and D&C Red No. 22 are safe for use in drugs and cosmetics. Therefore, elsewhere in this issue of the **Federal Register**, FDA is publishing a regulation that lists D&C Red No. 21 and D&C Red No. 22 for these uses. The regulation set forth below will postpone the November 30, 1982 closing date for the provisional listing of these color additives until March 1, 1983. This postponement will provide sufficient time for receipt and evaluation of comments or objections submitted in response to the regulation that lists D&C Red No. 21 and D&C Red No. 22 for use in drugs and cosmetics.

Because of the shortness of time until the November 30, 1982 closing date, FDA concludes that notice and public procedure on this regulation are impracticable. Moreover, good cause exists for issuing this postponement as a final rule because the agency has concluded that D&C Red No. 21 and D&C Red No. 22 are safe for their intended use under the Color Additive Amendments of 1960. This regulation will permit the uninterrupted use of this color additive until March 1, 1983. To prevent any interruption in the provisional listings of D&C Red No. 21 and D&C Red No. 22 and in accordance with 5 U.S.C. 553(d)(1) and (3), this regulation is being made effective on November 29, 1982.

List of Subjects in 21 CFR Part 81

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

Therefore, 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), Part 81 is amended as follows:

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

§ 81.1 [Amended]

1. In § 81.1 *Provisional lists of color additives,* by revising the closing date for D&C Red No. 21 and D&C Red No. 22 in paragraph (b) to read March 1, 1983.

§ 81.27 [Amended]

2. In § 81.27 *Conditions of provisional listing,* by revising the closing date for D&C Red No. 21 and D&C Red No. 22 in paragraph (d) to read March 1, 1983.

Effective date. This final rule is effective November 29, 1982.

(Sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)).

Dated: November 16, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-32728 Filed 11-26-82; 10:58 am]

BILLING CODE 4160-01-M

---

21 CFR Part 178

[Docket No. 81F-0404]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for