after publication in the FEDERAL REGISTER (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§ 910.440 Lemon Regulation 140.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period April 9, 1978 through April 15, 1978, is established at 250,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

2. Paragraph (a) of § 910.439 Lemon Regulation 139 (43 FR 13492) is amended to read as follows: "The quantity of lemons grown in California and Arizona which may be handled during the period April 2, 1978 through April 8, 1978, is established at 255,000 cartons."

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)

Dated: April 6, 1978.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-9532 Filed 4-6-78; 11:56 am]

[7590-01]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

[Docket No. RM-50-3]

PART 51—LICENSING AND REGULATORY POLICY AND PROCEDURES FOR ENVIRONMENTAL PROTECTION

Environmental Effects of the Uranium Fuel Cycle

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of oral argument.

SUMMARY: The Hearing Board will hold oral argument for the purpose of according the parties to this proceeding (42 FR 26987; May 26, 1977), the opportunity to request cross-examination of particular witnesses who have testified in this proceeding on specific factual issues relating to the environmental effects of the uranium fuel cycle.

DATE: Oral argument will be held on Thursday, April 20, 1978, at 10 a.m.

ADDRESS: Oral argument will be held in the Commission's Hearing Room, 5th floor, East West Towers, 4350 East-West Highway, Bethedsa, Md.

FOR FURTHER INFORMATION CONTACT:

Dr. John H. Buck, 202-492-7664.

MEMORANDUM AND ORDER

MARCH 30, 1978.

In the matter of amendment of 10 CFR Part 51 licensing of production and utilization facilities, (Environmental Effects of the Uranium Fuel Cycle), Docket No. RM 50-3.

The Hearing Board will hold oral argument on Thursday, April 20, 1978, at 10 a.m., in the Commission's Hearing Room, 5th floor, East West Towers, 4350 East-West Highway, Bethesda, Md., for the purpose of according the parties to this proceeding the opportunity to request cross-examination of particular witnesses who have testified in this proceeding on specific factual issues.

All parties requesting cross-examination will be required tc demonstrate the need for such cross-examination in accordance with the NRC's directive in January, 1978, to the Hearing Board.

The Hearing Board will require those parties requesting cross-examination to submit to the Hearing Board by April 12, 1978, a written statement of intention to request cross-examination, and to briefly identify the particular witness and specific factual issues to which such cross-examination will be directed. We will also require the requesting party to serve a copy of their statement directly on the party who sponsored the witness sought for cross-examination. At the oral argument, the parties requesting cross-examination will be expected to demonstrate with particularity that the cross-examination requested is necessary to develop an adequate record for sound discussion.

Upon conclusion of this oral argument, we will also allow the parties to this proceeding a brief opportunity to express their views on the need to hold rebuttal hearings.

Parties desiring to request cross-examination will make their argument in the same order of appearance as listed in our Memorandum and Order of January 4, 1978. Expression of views on the need for rebuttal hearings will be presented in the same order of appearance.

Parties opposing requests for cross-examination will be permitted to state their opposition to the requests after completion of all arguments in favor of cross-examination.

It is so ordered.

For the Hearing Board.

ROMAYNE M. SKRUTSKI,
Secretary to the Hearing Board.

[FR Doc. 78-9259 Filed 4-6-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0276]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

D&C Orange No. 4; Confirmation of Effective Date and Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of November 1, 1977, of a regulation concerning the use of D&C Orange No. 4 in externally applied drugs and cosmetics. In response to objections to the listing regulation, the specifications for total color and the sum of volatile matter and chloride and sulfates (as sodium salts) have been revised.

DATES: Effective date confirmed: November 1, 1977. Revision effective date: April 7, 1978.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of September 30, 1977 (42 FR 52395) added §§ 74.1254 and 74.2254 (21 CFR 74.1254 and 74.2254) to subparts B and C of part 74 (21 CFR part 74) to provide for safe use of of D&C Orange No. 4 in externally applied drugs and cosmetics and amended § 81.1(b) (21 CFR 81.1(b)) by deleting D&C Orange No. 4 from the provisionally listed colors. The regulation also amended the identity nomenclature and specifications for the certification of D&C Orange No. 4 under

§ 82.1254 (21 CFR 82.1254) to reference § 74.1254.

Two objections were filed in response to the order. A hearing was not requested. One letter, received from a manufacturer of the color and supported by a second letter from a copetitioner for listing of the color, objected to the limitations placed on the specifications for D&C Orange No. 4. The objections stated that total color should be "not less than 87 percent" instead of "90 percent" and that the sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts) should be "not more than 13 percent" instead of "10 percent." The objections further noted that under provisional listing those specifications for D&C Orange No. 4 were 85 percent and 15 percent, respectively. The objections state that the increase in labor and energy required for all batches of D&C Orange No. 4 to meet the specifications of 90 percent for total color and 10 percent for volatile matter and salts would serve only to lower the content of moisture and salt and would lead to increased expenses to producers and consumers.

After evaluating the objections and reviewing the available data, the Commissioner concurs that specifications for the color may be safely revised by the reduction of the specification for total color from 90 percent to 87 percent and an increase of the specifications for volatile matter (water) plus salts (sodium chloride and sodium sulfate) from 10 percent to 13 percent.

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 authority delegated to the Commissioner (21 CFR 5.1), there being no other objections or any request for a hearing in response to the order of September 30, 1977, the amendments to parts 74, 81, and 82 promulgated thereby became effective on November 1, 1977, and part 74 is amended in § 74.1254(b) by revising the listings therein for "sum of volatile matter" and "total color," to read as follows:

§ 74.1254 D&C Orange No. 4.

* * * * *

(b) * * *

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

* * * * *

Total color, not less than 87 percent.

* * * * *

Effective dates: (1) The amendments promulgated by the regulation of September 30, 1977, became effective on November 1, 1977; (2) the amendment set forth above is effective April 7, 1978.

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

Dated: March 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-8941 Filed 4-6-78; 8:45 am]

[4110-03]

[Docket No. 76N-0366]

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

Provisionally Listed Color Additives; Postponement of Closing Dates; Restatement of Conditions for Continued Provisional Listing

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the color additive regulations by extending the closing dates for four color additives (D. & C. Red No. 6, D. & C. Red No. 7, D. & C. Red No. 30 and caramel) and revising the dates by which certain reports must be submitted to the Food and Drug Administration. This action permits the continued use of these color additives until the new closing dates and amends the color additive regulations by updating the conditions that certain color additives must meet to remain on the provisional list.

EFFECTIVE DATE: April 7, 1978.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of December 13, 1977 (42 FR 62497), the Commissioner of Food and Drugs, on his own initiative, proposed to postpone the closing date for the use of five provisionally listed color additives beyond January 31, 1978. The proposed postponement was conditioned on the completion of appropriate scientific investigations and the submission of data to FDA on a prescribed schedule. The proposal also discussed the extent to which the petitioners have complied with the conditions of provisional listing that are set forth in § 81.27 *Conditions of provisional listing of additives* (21 CFR 81.27), and it proposed to revise certain of these conditions. The conditions in § 81.27 were initially prescribed in regulations published in the FEDERAL REGISTER of February 4, 1977 (42 FR).

In response to the proposal the Commissioner received one comment from the Environmental Defense Fund which contended that the closing date for the provisional listing of lead acetate should not be extended beyond January 31, 1978 because lead acetate is a known carcinogen. An analysis of this comment was subsequently received on January 27, 1978 from Combe, Inc., a manufacturer of lead acetate hair colors. The provisional listing of lead acetate, including a discussion of these comments, was considered in a separate document that was published in the FEDERAL REGISTER of March 3, 1978 (43 FR 8790).

The petitioners for caramel have recently requested that the proposed deadline of March 31, 1978 for the submission of the full written report on the subchronic study for caramel be extended for a short time because unforeseen problems have delayed its completion. In view of the short amount of time necessary to furnish the final report, the Commissioner concludes that a 30-day extension of the deadline for the final report is reasonable. This short additional extension to April 30, 1978, however, will not effect the "interim" closing date for caramel which is being extended as originally proposed to July 31, 1978.

In the absence of other comments, the Commissioner advises that the dates for submission of data and "interim" closing dates for the three remaining color additives discussed in the December 13, 1977 proposal are being extended as proposed. These three color additives include: D. & C. Red No. 6, D. & C. Red No. 7, and D. & C. Red No. 30. In addition, as proposed, the regulations set forth below add a new paragraph (e) to § 81.27 prescribing additional testing requirements to be met as conditions of the continued provisional listing of F.D. & C. Red No. 3 and D. & C. Red No. 33.

Certain conditions of § 81.27, for continued provisional listing of the color additives, established on February 4, 1977, have been complied with and are now obsolete. Additionally, the provisional listing of certain colors has been terminated since February 4, 1977. The regulation set forth below reflects these actions by deleting § 81.27(a) and reserving it for future use and deleting certain listings for colors from the requirements of paragraphs (b), (c), and (d) of § 81.27.

Therefore, under the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L.

86-316; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), § 81.27 is amended by revoking paragraph (a) and reserving it for future use; by revising paragraphs (b), (c), and (d); and by adding new paragraph (e), to read as follows:

§ 81.27 Conditions of provisional listing.

(a) [Reserved]

(b) The closing date for caramel is postponed until July 31, 1978, while a subchronic study is conducted and evaluated, and for lead acetate until December 31, 1978, while a short-term skin penetration study is conducted and evaluated, and subject to compliance with the requirements of this paragraph.

(1) At least one petitioner for caramel shall agree in writing by March 7, 1977 to undertake the subchronic study on the color additive.

(2) A full written report on the subchronic study for caramel shall be submitted by April 30, 1978, and on the short-term skin penetration study for lead acetate by September 30, 1978, to the Division of Food and Color Additives (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential of the color additives to cause adverse effects.

(c) The closing date for the following three color additives is postponed until October 31, 1978, while chemistry data and analytical methods to establish specifications for them are developed and evaluated, and subject to compliance with the requirements of this paragraph: D. & C. Red No. 6, D. & C. Red No. 7, and D. & C. Red No. 30.

(1) At least one petitioner for each of the three color additives listed in paragraph (c) of this section shall agree in writing by March 7, 1977 to undertake to develop the necessary chemistry data and analytical methods for the color additives.

(2) The required chemistry data and analytical methods shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, by July 31, 1978.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate a potential for the color additives to cause adverse effects.

(d) The closing date for the following 25 color additives is postponed until January 31, 1981, while chronic toxicity feeding studies for 24 of the colors and, in the case of caramel, a lifetime mouse skin-painting study, are conducted and evaluated, and subject to compliance with the requirements of this paragraph: F.D. & C. Yellow No. 5, F.D. & C. Yellow No. 6, D. & C. Yellow No. 10, F.D. & C. Red No. 3, D. & C. Red No. 6, D. & C. Red No. 7, D. & C. Red No. 8, D. & C. Red No. 9, D. & C. Red No. 19, D. & C. Red No. 21, D. & C. Red No. 22, D. & C. Red No. 27, D. & C. Red No. 28, D. & C. Red No. 30, D. & C. Red No. 33, D. & C. Red No. 36, D. & C. Red No. 37, F.D. & C. Green No. 3, D. & C. Green No. 5, D. & C. Green No. 6, F.D. & C. Blue No. 1, F.D. & C. Blue No. 2, D. & C. Orange No. 5, D. & C. Orange No. 17, and caramel.

(1) At least one petitioner for each of the 25 color additives listed in paragraph (d) of this section shall agree in writing by March 7, 1977 to undertake the required studies on the color additives.

(2) The petitioner undertaking the studies shall submit a protocol for the conduct of the studies to the Division of Food and Color Additives (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, for review and acceptance or rejection, by April 5, 1977.

(3) An initial progress report of the studies on the color additives shall be submitted to the Division of Food and Color Additives by December 31, 1977. Further progress reports shall be submitted at 6-month intervals thereafter. A full report of the studies conducted on the color additives shall be submitted to the Division of Food and Color Additives by August 4, 1980.

(4) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate potential for the color additives to cause adverse effects.

(e) The closing date for the following two color additives is postponed until January 31, 1981, while multigeneration reproduction studies are conducted and evaluated, and subject to compliance with the requirements of this paragraph: F.D. & C. Red No. 3 and D. & C. Red No. 33.

(1) At least one petitioner for each of the two color additives listed in paragraph (e) of this section shall agree in writing by May 8, 1978, to undertake multigeneration reproduction studies on the color additives.

(2) An initial progress report of the studies on the color additives shall be submitted by July 1, 1978 and at 6-month intervals thereafter. A full report of the studies conducted on the color additives shall be submitted to the Division of Food and Color Additives by August 4, 1980.

(3) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate potential for the color additives to cause adverse effects.

Effective date: April 7, 1978.

(Title II, Pub. L. 86-316; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: March 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-8954 Filed 4-6-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0131]

BEESWAX

Affirmation of GRAS Status as a Direct Human Food Ingredient

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule affirms that beeswax is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review being conducted by the agency.

EFFECTIVE DATE: May 8, 1978.

ADDRESS: Written objections to the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 29, 1977 (42 FR 38609), a proposal was published to affirm that beeswax (yellow and white) is generally recognized as safe for use as a direct human food ingredient. The proposal was based on safety information developed by the Select Committee on GRAS substances. The proposal was published in accord with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), relating to the affirmation of GRAS food ingredients, copies of the Scientific Literature Review on beeswax, data on mutagenic evaluation, and the report of the Select Committee on GRAS substances have been made available for public review in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Copies of these documents have

also been made available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing to affirm the GRAS status of beeswax, the Commissioner of Food and Drugs gave public notice that he was unaware of any prior-sanctioned food ingredient use for this ingredient other than for the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approval granted by the U.S. Department of Agriculture or the Food and Drug Administration prior to September 6, 1958, were given notice to submit proof of such a sanction so that the safety of prior-sanctioned uses could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of beeswax (yellow and white) approved by issuance of an appropriate regulation under Part 181 (21 CFR 181) "Prior-Sanctioned Food Ingredient," provided prior-sanctioned use could be affirmed as safe on the basis of data now available to the Commissioner. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert sanction at any future time.

No reports of a prior-sanctioned use for beeswax were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of beeswax under conditions different from those set forth in this regulation has been waived.

No comments were received in response to the Commissioner's proposal and supporting data and information on beeswax (yellow and white). The Commissioner therefore concludes that no change in the proposal to affirm the GRAS status of beeswax (yellow and white) is warranted. Accordingly, it is being promulgated without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

§ 172.510 [Amended]

1. In Part 172, § 172.510 *Natural flavoring substances and natural substances used in conjunction with flavors,* by deleting the entry for "Beeswax, white (Cire d'abeille)" from the list of substances in paragraph (b).

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§ 182.1973, 182.1975 [Deleted]

2. In Part 182, by deleting § 182.1973 *Beeswax* and § 182.1975 *Bleached beeswax.*

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. In Part 184, by adding new § 184.1973 to read as follows:

§ 184.1973 Beeswax (yellow and white).

(a) Beeswax (CAS Registry No. MX 8012-89-3 and MX 8006-40-4) is a secretory product of honey bees used as a structural material in honeycombs. Beeswax is prepared from honeycombs after removal of the honey by draining or centrifuging. The combs are melted in hot water or steam or with solar heat, and strained. The wax is refined by melting in hot water to which sulfuric acid or alkali may be added to extract impurities. The resulting wax is referred to as yellow beeswax. White beeswax is produced by bleaching the constituent pigments of yellow beeswax with peroxides, or preferably it is bleached by sun light.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. 1972.[1]

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, as a lubricant as defined in § 170.3(o)(18) of this chapter, and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(d) The ingredient is used in food, in accordance with § 184.1(b)(1) of this chapter, at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of: 0.065 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 0.005 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter; 0.04 percent for hard candy as defined in § 170.3(n)(25) of this chapter; 0.1 percent for soft candy as defined in § 170.3(n)(38) of this chapter; and 0.002 percent or less for all other food categories.

Effective date. This regulation is effective May 8, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

[1] Copies may be obtained from: National Academy of Sciences, 2101 Constitution Avenue NW., Washington, D.C. 20037.

Dated: March 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on July 10, 1973 and is on file in the Rederal Register's library.

[FR Doc. 78-8951 Filed 4-6-78; 8:45 am]

[1505-01]

[Docket No. 76N-0460]

PART 173—SECONDARY DIRECT FOOD ADDITIVES IN FOOD FOR HUMAN CONSUMPTION

Subpart D—Specific Usage Additives

Correction

In FR Doc. 78-6039 appearing at page 11301 in the FEDERAL REGISTER issue of Friday, March 17, 1978, please make the following corrections:

At page 11302, in the third column under paragraph 6., in the third line of the second paragraph "oxzone" should be changed to "ozone";

At page 11305, in the 31st line of the third column, the word "degrated" should be changed to "degraded";

At page 11315, in the 11th line of the third column, the word "ustin" should be changed to "using"; and

At page 11317, in § 173.345(c)(1)(i), "chloropentafluroethane" should appear as "chloropentafluoroethane".

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 77N-0060]

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

Radioactive Drugs for Certain Research Uses; Amended Reporting Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This amendment revises the reporting requirements for research studies in which radioactive drugs are used. It deletes the requirement for detailed measurements and calculations for each subject in the study; instead, it permits submission of data on a representative subject. The effect will be to decrease the burden in reporting required of the