1. The authority citation for Part 399 continues to read as follows:

Authority: Pub. L. 96–72, 93 Stat. 503, 50 U.S.C. App. 2401 *et seq.*, as amended by Pub. L. 97–145 of December 29, 1981 and by Pub. L. 99–64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95–223, 50 U.S.C. 1701 *et seq.*, E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99–440 (October 2, 1986); E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986).

**§ 399.1 [Amended]**

2. In the Commodity Control List (Supplement No. 1 to 399.1), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1531A is amended by adding in paragraph (e)(3)(ii) the words "or less" after the words "50 watts" and after the words "300 watts".

Dated: June 30, 1987.

**Vincent F. DeCain,**

*Deputy Assistant Secretary for Export Administration.*

[FR Doc. 87–15153 Filed 7–2–87; 8:45 am]

BILLING CODE 3510–DT–M

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Part 201

**[Release Nos. 33–6723; 34–24637; 35–24417; 39–2100; IC–15821; IA–1073]**

### Commission Rules of Practice

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission is correcting Commission Rule of Practice 6(b), 17 CFR 201.6(b).

**EFFECTIVE DATE:** July 6, 1987.

**FOR FURTHER INFORMATION CONTACT:** Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549, (202) 272–2600.

**SUPPLEMENTARY INFORMATION:** The Commission Rule of Practice 6(b) concerning service of notice for proceedings and hearings is incorrect as it appears in the current provisions of the Code of Federal Regulations. In order to clarify the requirements of Rule 6(b), it is set forth in its entirety.

The foregoing action relates solely to a correction of the rules of agency procedure and practice; therefore, notice and request for comment pursuant to the Administrative Procedure Act, 5 U.S.C. 551, *et seq.* are unnecessary. Moreover, because the sentence to be added was inadvertently deleted from the rule in 1978 and the Commission has been acting under the presumption that the provision was in place, the Commission finds good cause to make 17 CFR 201.6(b), as corrected, effective July 6, 1987.

**List of Subjects in 17 CFR Part 201**

Administrative Practice and Procedure, Investigations, Securities

**PART 201—[AMENDED]**

**Text of Amendment**

Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 201 is amended by adding the following citation:

Authority: Secs. 19, 23, 48 Stat. 85, as amended, 901, as amended, sec. 20, 49 Stat. 1173, secs. 28, 211, 54 Stat. 841, 855; 15 U.S.C. 77s, 78w, 79t, 77sss, 80a–37, 80b–11 * * * § 201.6 also issued under 15 U.S.C. 77h, 77ttt, 78d–1, 78d–2, 78v, 79s, 80a–40, 80b–12.

2. In § 201.6 paragraph (b) is revised as follows:

**§ 201.6 [Amended]**

* * * * *

(b) *Notice of hearing; service of notice.* The time and place for any hearing in a proceeding shall be fixed with due regard for the public interest and the convenience and necessity of the parties, the participants or their representatives. It is the policy of the Commission that in a proceeding under any provision of the Public Utility Holding Company Act of 1935, the Investment Company Act of 1940 (except section 9(b) thereof), section 206A of the Investment Advisers Act of 1940, section 8 of the Securities Act of 1933, or sections 305 or 307 of the Trust Indenture Act of 1939, the hearing should normally be held in Washington, D.C. Each party or person entitled to notice shall be given notice of hearing a reasonable time in advance of the hearing, and such notice may be given by personal service, by confirmed telegraphic notice or, in any proceedings other than those pursuant to section 8 of the Securities Act of 1933 or section 305 or 307 of the Trust Indenture Act of 1939, by registered mail or certified mail, addressed to his last known business or residence address or to the address of his agent for service.

* * * * *

By the Commission.

June 24, 1987.

**Shirley E. Hollis,**

*Assistant Secretary.*

[FR Doc. 87–14929 Filed 7–2–87; 8:45 am]

BILLING CODE 8010–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### 18 CFR Part 11

**[Docket Nos. RM86–2–002, –003, –004]**

### Revision of the Billing Procedures for Annual Charges for Administering Part I of the Federal Power Act and to the Methodology for Assessing Federal Land Use Charges; Order Granting Rehearing for Purpose of Further Consideration

Issued: June 30, 1987.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Order granting rehearing for further consideration.

**SUMMARY:** On May 8, 1987, the Federal Energy Regulatory Commission issued a final rule to revise the billing procedures for annual charges for administering Part I of the Federal Power Act, the billing procedures for charges for Federal dam and land use, and the methodology for assessing Federal land use charges.

In this order, the Commission grants rehearing of its decision solely for the purpose of further consideration.

**EFFECTIVE DATE:** June 30, 1987.

**FOR FURTHER INFORMATION CONTACT:** James R. Keegan, Federal Energy Regulatory Commission, Office of the General Counsel, 825 North Capitol Street, NE., Washington, DC 20426, (202) 357–8542.

Before Commissioners: Martha O. Hesse, Chairman; Anthony G. Sousa, Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

On May 8, 1987, the Commission issued a final rule that amended Part 11 of its regulations under the Federal Power Act (Act). The final rule revised the billing procedures for annual charges for administering Part I of the Act, the billing procedures for charges for Federal dam and land use, and the methodology for assessing Federal land use charges.[1]

Pursuant to 18 CFR 385.713 (1986), the Edison Electric Institute, Southern California Edison Company, and Pacific Gas and Electric filed separate requests for rehearing of the above-captioned proceeding. In order to review more fully the arguments raised, the Commission grants rehearing of the order solely for the purpose of further

[1] Order 469, 52 FR 18201 (May 14, 1987) III FERC Stats. and Regs. ¶30,741 (1987).

consideration. This action does not constitute a grant or denial of the requests on their merit in whole or in part.

*The Commission orders:*

Rehearing of the Commission order in the above-captioned proceeding is granted solely for the purpose of further consideration. Because this order is not a final order on rehearing, no response to the requests will be entertained by the Commission. *See* § 385.713(d) (1986) of the Commission's rules of practice and procedure.

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 87-15192 Filed 7-2-87; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 81

**[Docket No. 76N-0366]**

### Provisional Listing of D&C Red No. 33 and D&C Red No. 36; 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. 33 and D&C Red No. 36 for use as color additives in drugs and cosmetics. The new closing date will be September 4, 1987. FDA has decided that this brief postponement is necessary to provide time for the preparation of documents that will explain the bases for the agency's decisions concerning the conditions under which these color additives may be safely used.

**EFFECTIVE DATE:** Effective July 6, 1987, the new closing date for D&C Red No. 33 and D&C Red No. 36 will be September 4, 1987.

**FOR FURTHER INFORMATION CONTACT:** Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5676.

**SUPPLEMENTARY INFORMATION:** FDA established the current closing date of July 6, 1987, for the provisional listing of D&C Red No. 33 and D&C Red No. 36 by regulation published in the **Federal Register** of May 1, 1987 (52 FR 15945). FDA extended the closing date for these color additives until July 6, 1987, to provide time for completion of the agency's review and evaluation of the data concerning the drug and cosmetic uses of these color additives, and for publication of a regulation in the **Federal Register** regarding the agency's final decision on the petitions for the permanent listing of these color additives. The regulation set forth below will postpone the July 6, 1987, closing date for the provisional listing of these color additives until September 4, 1987.

FDA has essentially completed its review and evaluation of available information relevant to the use of these color additives in drugs and cosmetics. The agency has concluded that the drug and cosmetic uses of D&C Red No. 33 and D&C Red No. 36 are safe. Thus, the agency has decided to permanently list the color additives for these uses. New certification specifications are also being developed for these color additives.

The agency has not yet completed documents fully describing the bases for each of these decisions and setting forth detailed conditions for use. Therefore, FDA believes that it is reasonable to postpone the closing date for these color additives until September 4, 1987, to provide time for the preparation and publication of appropriate **Federal Register** documents. The agency intends to publish these documents as soon as possible. FDA concludes that this short extension is consistent with the public health and the standards set forth for continuation of provisional listing in *McIlwain* v. *Hayes*, 690 F.2d 1041 (D.C. Cir. 1982).

Because of the shortness of time until the July 6, 1987, closing date, FDA concludes that notice and public procedure on this regulation are impracticable and that good cause exists for issuing the postponement as a final rule and for an effective date of July 6, 1987. This regulation will permit the uninterrupted use of these color additives until further action is taken. In accordance with 5 U.S.C. 553 (b) and (d) (1) and (3), this postponement is issued as a final regulation, effective on July 6, 1987.

**List of Subjects in 21 CFR Part 81**

Color additives, Cosmetics, Drugs.

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 81 is amended as follows:

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

1. The authority citation for 21 CFR Part 81 continues to read as follows:

**Authority:** Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note); 21 CFR 5.10.

**§ 81.1 [Amended]**

2. In § 81.1 *Provisional lists of color additives* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" appearing in the table in paragraph (b) to read "September 4, 1987".

**§ 81.27 [Amended]**

3. In § 81.27 *Conditions of provisional listing* by revising the closing dates for "D&C Red No. 33" and "D&C Red No. 36" in paragraph (d), introductory text table, to read "September 4, 1987".

Dated: June 26, 1987.

**John M. Taylor,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 87-14988 Filed 7-2-87; 8:45 am]

BILLING CODE 4160-01-M

### 21 CFR Parts 182 and 184

**[Docket No. 81N-0312]**

### Beta-Carotene; Affirmation as Generally Recognized as Safe

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is affirming that *beta*-carotene 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 conducted by the agency.

**DATES:** Effective August 5, 1987. The Director of the Federal Register approves the incorporation by reference of a certain publication in 21 CFR 184.1245 effective as of August 5, 1987.

**ADDRESSES:** Copies of the scientific literature review and the report of the Select Committee on GRAS Substances on *beta*-carotene have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are available for purchase from the National

Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161.

**FOR FURTHER INFORMATION CONTACT:** Donna A. Dennis, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 26, 1982 (47 FR 47435), FDA published a proposal to affirm that *beta*-carotene is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with the announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the report of the Select Committee on GRAS Substances (the Select Committee) on *beta*-carotene have been made available for public review in the Dockets Management Branch (HFA–305) (address above). Copies of these documents are available for purchase from the National Technical Information Service.

In addition to proposing to affirm the GRAS status of *beta*-carotene, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for *beta*-carotene were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received two comments in response to the proposed rule. A summary of these comments and the agency's responses follow:

One comment questioned the effect of the agency's proposal for *beta*-carotene on carrot oil as described in § 73.300 *Carrot oil* (21 CFR 73.300) and § 182.20 *Essential oils, oleoresins (solvent free), and natural extractives including distillates* (21 CFR 182.20). The comment noted that its product, carrot oil, is a mixture of carotenoids and is produced by extraction from edible carrots and is not synthetically manufactured.

The agency advises that carrot oil covered by 21 CFR 73.300 and 182.20 is not affected by the final rule for *beta*-carotene. As noted by the comment, carrot oil is a mixture of carotenoids and is produced by extraction of edible carrots. Thus, it is a different product from *beta*-carotene described in new § 184.1245.

A second comment stated that the Select Committee's final report underestimated the daily amount of *beta*-carotene consumed by infants. The comment submitted a 4½-ounce jar of baby food (carrots) to FDA for analysis. The comment stated that the jar contained about 25,000 international units of vitamin A, which is equivalent to 14 milligrams of *beta*-carotene. The comment went on to describe the case of an infant who consumed three or more jars of carrots each day, which amounted to at least 45 milligrams of *beta*-carotene. The comment reported that the infant had developed carotenemia (orange pigmentation of the skin) from eating the baby food containing carrots.

This comment also cited two references on *beta*-carotene (and vitamin A). One of the references described liver concentrations, of *beta*-carotene in individuals who died after an acute, traumatic event as well as in individuals who died from chronic disease (Ref. 1). The other publication discussed the association of carotenemia and menstrual disorders in women (Ref. 2).

The agency has reviewed this comment in light of the Select Committee's final report and of the published articles cited in the comment. As reported in the proposal (47 FR 47436), the Select Committee considered the estimated per capita intake of *beta*-carotene from all sources to average approximately 2.3 milligrams per day. This estimate is representative of the long-term eating patterns of the entire populaition expressed on daily basis. However, as the Select Committee indicated in its report, substantially larger amounts of *beta*-carotene may be ingested in diets rich in colored vegetables (*id*). The Select Committee also noted that, using other data on intake, the National Research Council estimated that the daily consumption of added carotene by unfants and small children up to 23 months of age ranged from 1 milligram to 26 milligrams (Ref. 4). Nevertheless, the Select Committee concluded that there was no evidence of hazard to infants, children, or the public at large when the substance is used at either current levels or those reasonably expected in the future (47 FR 47437).

The agency has considered the comment's report of consumption of at least 45 milligrams a day of *beta*-carotene by an infant. FDA believes that the level of *beta*-carotene consumed by the infant was high and directly related to the child's above average consumption of carotene rich carrots. The agency has no basis to question the comment's assertion that the infant suffered from carotenemia. FDA is aware that carotenemia can develop as a result of sustained high levels of carotene consumption. However, the Select Committee stated, and the agency believes, that carotenemia is a harmles skin coloration cause by consumption of high levels of *beta*-carotene rather than an acute or chronic toxic effect. The agency also notes that the condition is reversible in 2 to 6 weeks after the high levels of carotene rich foods are omitted from the diet.

FDA also has reviewed the references cited in the comment. One of the references (Ref. 2) presented data on 10 women suggesting that carotenemia, resulting from the ingestion of an excessively high carotene diet, may be associated with the development of menstrual dysfunction. The patients who were able to modify their diet showed an improvement in their menstrual cycles. The author of the report theorized that carotenemia is possibly related to menstrual dysfunction but concluded that further investigation was needed to assess this hypothesis. Based on its review of this reference, the agency believes that the data in the study are inadequate to draw any conclusions on the association between carotenemia and menstrual dysfunction. The study was small (only 10 patients) and had numerous design deficiencies, including a lack of any controls.

The other reference (Ref. 1) discussed an article (Ref. 3) that reported carotene and vitamin A concentrations in liver specimens collected during autopsies in Washington, DC. The age group in which the carotene content of liver was lowest was children below the age of 2, and it was highest in children from 2 months to 10 years old and in adults over 70 years old. the vitamin A content of liver, in relation to age, followed a pattern similar to that of carotene. The paper suggest that the lower levels

observed in early infancy reflect limited reserves at birth, and the higher levels seen in children from 2 months to 10 years old and in adults over 70 years old may be the result of the use of vitamin supplements.

The agency found nothing in these references that could be considered evidence of acute or long-range toxicity. FDA has not been presented with any data or information that would cause it to alter its opinion that the current usage, as well as reasonably foreseeable future usage, of *beta*-carotene is safe. Consequently, FDA has not modified the regulation on *beta*-carotene as a result of this comment.

The agency advises that the food categories listed in the proposed regulation for *beta*-carotene as a nutrient were the uses reported in the National Academy of Sciences/National Research Council survey. They are not intended to be specific limitations or to preclude the use of this ingredient in other food categories. No data on the use of *beta*-carotene in additional food categories were submitted to the agency as comments on the proposal. Persons seeking FDA approval of new uses of this ingredient may submit a food additive or GRAS affirmation petition in accordance with § 171.1 or § 170.35 (21 CFR 171.1 or 170.35).

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

### References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Pipes, P., *Nutrition in Infancy and Childhood*, 2d Ed., p. 49, 1981.

2. Kemmann, E., "Amenorrhea Associated with Carotenemia, "*Journal of the American Medical Association*, 249:926–929, 1983.

3. Mitchell, G.V., M. Young, and C.R. Seward, "Vitamin A and Carotene Levels of a Selected Population in Metropolitan Washington, DC.," *American Journal of Clinical Nutrition*, 26:992–997, 1973.

4. "Evaluation of the Health Aspects of Carotene (*beta*-Carotene) as a Food Ingredient," Life Sciences Research Office, Federation of American Societies for Experimental Biology, p. 7, 1979.

### List of Subjects

*21 CFR Part 182*

Food ingredients, Spices and flavorings.

*21 CFR Part 184*

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR Parts 182 and 184 are amended as follows:

## PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

**Authority:** Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21, CFR 5.10, 5.61.

**§ 182.8245 [Removed]**

2. Part 182 is amended by removing § 182.8245 *Carotene.*

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

3. The authority citation for 21 CFR Part 184 continues to read as follows:

**Authority:** Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

4. Part 184 is amended by adding new § 184.1245 to read as follows:

**§ 184.1245 Beta-carotene.**

(a) *Beta*-carotene (CAS Reg. No. 7235–40–7) has the molecular formula $C_{40}H_{56}$. It is synthesized by saponification of vitamin A acetate. The resulting alcohol is either reacted to form vitamin A Wittig reagent or oxidized to vitamin A aldehyde. Vitamin A Wittig reagent and vitamin A aldehyde are reacted together to form *beta*-carotene.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in § 170.3(n)(10) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; and processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter. *Beta*-carotene may be used in infant formula as a source of vitamin A in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act or with regulations promulgated under section 412(g) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: June 23, 1987.

**Sanford A. Miller,**

*Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 87–15204 Filed 7–2–87; 8:45 am]

BILLING CODE 4160–01–M

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## 21 CFR Parts 510 and 522

## Animal Drugs, Feeds, and Related Products; Change of Sponsor

**AGENCY:** Food and Drug Administration.