21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

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 of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.1978 [Removed]

1. Part 182 is amended by removing § 182.1978 *Carnauba wax.*

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

2. Part 184 is amended by adding new § 184.1978, to read as follows:

§ 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008–015–869) is obtained from the leaves and buds of the Brazilian wax palm *Copernicia cerifera* Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C_{24} to C_{32} normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(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 an anticaking agent as defined § 170.3(o)(1) of this chapter; as a formulation aid as defined in § 170.3(o)(14) of this chapter; as a lubricant and release agent 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.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter; chewing gun as defined in § 170.3(n)(6) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; fresh fruits and fruit juices as defined in § 170.3(n)(16) of this chapter; gravies and sauces as defined in § 170.3(n)(24) of this chapter; processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter; and soft candy as defined in § 170.3(n)(38) of this chapter.

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

Effective date. This regulation shall be effective December 7, 1983.

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

Dated: October 19 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30036 Filed 11-4-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 81N-0341]

GRAS Status of Riboflavin and Riboflavin-5'-Phosphate (Sodium)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that riboflavin and riboflavin-5'-phosphate (sodium) are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 7, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1695 and 184.1697 effective on December 7, 1983.

FOR FURTHER INFORMATION CONTACT: Leonard C. Gosule, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 1982 (47 FR 40448), FDA published a proposal to affirm that riboflavin and riboflavin-5'-phosphate (sodium) are GRAS for use as direct human food ingredients. The proposal was published in accordance with the announced FDA 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 on riboflavin and riboflavin-5'-phosphate (sodium) and the report of the Select Committee on GRAS Substances (the Select Committee) on riboflavin and riboflavin-5'-phosphate (sodium) are 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 also are 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 riboflavin and riboflavin-5'-phosphate (sodium), FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients 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 these ingredients 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 riboflavin or riboflavin-5'-phosphate (sodium) were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of riboflavin or riboflavin-5'-phosphate (sodium) under conditions different from those set forth in this final rule has been waived.

No comments were received in response to the agency's proposal on these ingredients. The agency is therefore issuing the proposed regulation as a final rule with minor editorial changes.

The agency has previously determined under 21 CFR 25.24(d)(6) (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. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has 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, the agency has previously considered 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 defined by that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's finding 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 the threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavoring.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

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 of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended:

§ 182.8695 [Removed]

a. By removing § 182.8695 *Riboflavin.*

§ 182.8697 [Removed]

b. By removing § 182.8697 *Riboflavin-5-phosphate.*

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

2. Part 184 is amended:

a. By adding new § 184.1695, to read as follows:

§ 184.1695 Riboflavin.

(a) Riboflavin ($C_{17}H_{20}N_4O_6$, CAS Reg. No. 83–88–5) occurs as yellow to orange-yellow needles that are crystallized from 2*N* acetic acid, alcohol, water, or pyridine. It may be prepared by chemical synthesis, biosynthetically by the organism *Eremothecium ashbyii*, or isolated from natural sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 262, 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 foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

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

b. By adding new § 184.1697, to read as follows:

§ 184.1697 Riboflavin-5'-phosphate (sodium).

(a) Riboflavin-5'-phosphate (sodium) ($C_{17}H_{20}N_4O_8PNa.2H_2O$,CAS Reg. No 130–40–5) occurs as the dihydrate in yellow to orange-yellow crystals. It is prepared by phosphorylation of riboflavin with chlorophosphoric acid, pyrophosphoric acid, metaphosphoric acid, or pyrocatechol cyclic phosphate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 263, 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 milk products, as defined in § 170.3(n)(31) of this chapter, at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

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

Effective date. This regulation shall be effective December 7, 1983.

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

Dated: October 19, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30037 Filed 11-4-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 78N-0199]

GRAS Status of Pectins

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that pectins are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 7, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1588 effective on December 7, 1983.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 29, 1978 (43 FR 38591), FDA published a proposal to affirm that pectins are GRAS for use as direct human food ingredients. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

Subsequently, the agency published a tentative final rule in the **Federal Register** of August 13, 1982 (47 FR 35242), in which FDA proposed not to include levels of use or food categories in the GRAS regulation on pectins. The tentative final rule provided an opportunity for public comment on this change.

One comment was received from a food manufacturer in response to the tentative final rule. The comment noted that a semantic error was made in the description statement of the proposed regulation concerning type commercial preparation of pectin. The comment recommended that the word "and" be replaced by "or" in the fourth sentence of paragraph (a) of the regulation to reflect clearly the intent of the regulation concerning the source of the ingredient. The comment stated that the word "and" implies that pectin must be produced as a mixture from three sources instead of one or more of the three.

FDA agrees with this comment and has revised this final rule to reflect this change.

The agency has previously determined under 21 CFR 25.24(d)(6) (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. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has 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, the agency has previously considered the potential economic effects of this final rule. As announced in the tentative final rule, the agency has determined that the rule is not a major rule as determined by that Order. FDA 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 (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) a food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

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 of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.1775 [Removed]

1. Part 182 is amended by removing § 182.1775 *Sodium pectinate.*

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

2. Part 184 is amended by adding new § 184.1588, to read as follows:

§ 184.1588 Pectins.

(a) The pectins (CAS Reg. No. 9000-69-5) are a group of complex, high molecular weight polysaccharides found in plants and composed chiefly of partially methylated polygalacturonic acid units. Portions of the carboxly group occur as methyl esters, and the remaining carboxyl groups exist in the form of the free acid or, as its ammonium, potassium, or sodium (CAS Reg. No. 9000-59-8) salts, and in some types as the acid amide. Thus, the pectins regulated in this section are the high-ester pectins, low-ester pectins, amidated pectins, pectinic acids, and pectinates. Pectin is produced commercially by extracting citrus peel, apple pomace, or beet pulp with hot dilute acid (pH 1.0 to 3.5, 70° to 90° C). The extract is filtered, and pectin is then precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes spray- or roller-dried, or it is concentrated to be sold as liquid pectin.

(b) The ingredients meet the specifications of the Food Chemical Codex, 3d Ed. (1981), p. 215, 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 ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as emulsifiers as defined in § 170.3(o)(8) of this chapter and as stabilizers and thickeners as defined in § 170.3(o)(28) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

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

Effective date. This regulation shall be effective December 7, 1983.

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

Dated: October 19, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30036 Filed 11-4-83; 8:45 am]

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21 CFR Parts 182 and 184

[Docket No. 79N-0032]

GRAS Status of Lecithin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that lecithin is generally recognized as safe (GRAS) as a direct human food