

and belief, the submission complies with the requirements of § 12.85. The Bureau has also filed with the Dockets Management Branch a narrative statement setting forth its position on the issue for hearing and a summary of the type of evidence intended to be introduced in support of its position at the hearing.

Interested persons may obtain a copy of the narrative statement from the Dockets Management Branch at the address above. Persons may also examine the data filed in this matter (with the exception of any data identified as confidential) at the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

The prehearing conference and hearing session will be open to the public. Any participants may appear in person, or by or with counsel, or with other qualified representatives, and may be heard on relevant matters. Participants other than the Bureau of Foods shall disclose data and information on or before January 6, 1984, under § 12.85.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706(d), 70 Stat. 919 as amended, 74 Stat. 402-403 (21 U.S.C. 371(e), 376(d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is ordered that a formal evidentiary public hearing be held on the issue set forth in this notice.

Dated: November 1, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-30035 Filed 11-4-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 81N-0225]

GRAS Status of Carnauba Wax

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that carnauba wax 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 December 7, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1978 effective on December 7, 1983.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, 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 6, 1982 (47 FR 34164), FDA published a proposal to affirm that carnauba wax is GRAS for use as a direct human food ingredient. 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, data on the mutagenic evaluation, and the report of the Select Committee on GRAS Substances (the Select Committee) on carnauba wax 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 carnauba wax, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for this ingredient, other than for 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 prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of carnauba wax recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Parts 184 and 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 carnauba wax were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of carnauba wax under conditions different from those set forth in this final rule has been waived.

One comment was received in response to the proposal. The comment was from a food manufacturer who requested an expansion of the carnauba wax regulation to include the use of the ingredient as a fixative or encapsulating agent for volatile flavoring agents that are used to flavor sauces and gravies.

The agency has reviewed the use described in the comment and finds that

this use would result in the presence of a low level of carnauba wax in sauces and gravies. The consumer exposure to carnauba wax resulting from this use is not expected to add significantly to consumer exposure to carnauba wax resulting from its other uses in food. Further, the increase in exposure would be well within the safe levels for this food ingredient established by the safety studies on carnauba wax. The agency concludes that this new use is GRAS. Because the agency considers encapsulating agents to be carriers of flavors, FDA has included in 21 CFR 184.1978 the requested use of carnauba wax as a formulation aid as defined in § 170.3(o)(14) (21 CFR 170.3(o)(14)) for use in gravies and sauces as defined in § 170.3(n)(24).

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 determined 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 a 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 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

§ 182.1978 [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. 008-015-889) 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 C₂₄ to C₃₂ 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 gum 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]

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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 2N 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) ($C_{17}H_{20}N_4O_8PNa \cdot 2H_2O$, 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

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.