ammonia. Ammonium chloride is crystallized from the solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave, NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 dough strengthener as defined in § 170.3(o)(6) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; and a processing aid as defined in § 107.3(o)(24) of this chapter.

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

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

d. By adding new § 184.1139, to read as follows:

§ 184.1139 Ammonium hydroxide.

(a) Ammonium hydroxide (NH_4OH, CAS Reg. No. 1336-21-6) is produced by passing ammonia gas into water.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing pratice. 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 pactice conditions of use:

(1) The ingredient is used as a leavening agent as defined in § 170.3(o)(17) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used as a boiler water good additive at levels not to exceed current good manufacturing practice.

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

e. By adding new § 184.1141a, to read as follows:

§ 184.1141a Ammonium phosphate, monobasic.

(a) Ammonium phosphate, monobasic ($NH_4H_2PO_4$, CAS Reg. No. 7722-76-1) is manufactured by reacting ammonia with phosphoric acid at a pH below 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2110 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 dough strengthener as defined in § 170.3(o)(6) of this chapter and a pH control agent as defined in § 170.3(o)(23) of this chapter.

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

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

f. By adding new § 184.1141b, to read as follows:

§ 184.1141b Ammonium phosphate, dibasic.

(a) Ammonium phosphate, dibasic ($(NH_4)_2HPO_4$, CAS Reg. No. 7783-28-0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 dough strengthener as defined in § 170.3(o)(6) of this chapter; a firming agent as defined in § 170.3(o)(10) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; a pH control agent as defined in § 170.3(o)(23) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

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

(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 19, 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 24, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30814 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 78N-0071]

GRAS Status of Carbonates and Bicarbonates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that calcium carbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, sodium sesquicarbonate, and ground limestone 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 19, 1983.

The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1191, 184.1409, 184.1613, 184.1619,

184.1736, 184.1742, and 184.1792 effective on December 19, 1983.

FOR FURTHER INFORMATION CONTACT: Leo F. Mansur, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 13, 1978 (43 FR 25438), FDA published a proposal to affirm that calcium carbonate, potassium bicarbonate, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium sesquicarbonate are GRAS for use as direct human food ingredients, and that sodium carbonate and sodium bicarbonate are GRAS for use in indirect 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 31, 1982 (47 FR 38349), in which FDA proposed not to include the levels of use or, in some instances, the food categories and technical effects that appeared in the proposal. The tentative final rule also adopted a change in specifications for calcium carbonate and tentatively affirmed that ground limestone is GRAS as a direct human food ingredient. The tentative final rule provided an opportunity for public comment on these changes.

One comment was received in response to the agency's tentative final rule. The comment pointed out that several analytical limits for sodium sesquicarbonate, in the 3d edition of the Food Chemicals Codex, were different from those in the 2d edition. These included assay ranges for sodium bicarbonate of not less than 35.0 percent and not more than 38.6 percent as compared to a range of not less than 35.5 percent or not more than 37.2 percent in the 2d edition; ranges for sodium carbonate of not less than 46.4 percent or not more than 50.0 percent as compared to a range of not less than 47.0 percent or not more than 48.5 percent in the 2d edition; and water ranges between 13.8 and 16.7 percent as compared to a range between 15.2 and 16.2 percent in the 2d edition.

The agency notes that these changes resulted from use of a new, more accurate method of analysis for the sodium bicarbonate content of sodium sesquicarbonate. However, the agency was aware of these changes and determined that they were not significant. Furthermore, the modifications of the assay ranges do not result in any need for changes in the regulation because the tentative final rule established the Food Chemicals Codex, 3d edition, which contains these modifications, as the reference for the compound specifications. The agency is therefore issuing this final rule based on the tentative final rule with no 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 the 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) 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

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing the entries for "Sodium bicarbonate" and "Sodium carbonate."

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entry for "Sodium carbonate."

§§ 182.1191, 182.1613, 182.1619, 182.1736, 182.1742, 182.1792, and 182.8191 [Removed]

c. By removing § 182.1191 *Calcium carbonate*, § 182.1613 *Potassium bicarbonate*, § 182.1619 *Potassium carbonate*, § 182.1736 *Sodium bicarbonate*, § 182.1742 *Sodium carbonate*, § 182.1792 *Sodium sesquicarbonate*, and § 182.8191 *Calcium carbonate*.

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

2. Part 184 is amended:

a. By adding new § 184.1191, to read as follows:

§ 184.1191 Calcium carbonate.

(a) Calcium carbonate ($CaCO_3$, CAS Reg. No. 471-34-1) is prepared by three common methods of manufacture:

(1) As a byproduct in the "Lime soda process";

(2) By precipitation of calcium carbonate from calcium hydroxide in the "Carbonation process"; or

(3) By precipitation of calcium carbonate from calcium chloride in the "Calcium chloride process".

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 46, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from that set

forth in Part 181 of this chapter, do not exist or have been waived.

b. By adding new § 184.1409, to read as follows:

§ 184.1409 Ground limestone.

(a) Ground limestone consists essentially (not less than 94 percent) of calcium carbonate ($CaCO_3$) and is prepared by the crushing, grinding, and classifying of naturally occurring limestone.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 173, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

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

c. By adding new § 184.1613, to read as follows:

§ 184.1613 Potassium bicarbonate.

(a) Potassium bicarbonate ($KHCO_3$, CAS Reg. No. 298–14–6) is made by the following processes:

(1) By treating a solution of potassium hydroxide with carbon dioxide;

(2) By treating a solution of potassium carbonate with carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 formulation aid as defined in § 170.3(o)(14) of this chapter; nutrient supplemlent as defined in § 170.3(o)(20) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

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

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

d. By adding new § 184.1619, to read as follows:

§ 184.1619 Potassium carbonate.

(a) Potassium carbonate (K_2CO_3, CAS Reg. No. 584–08–7) is produced by the following methods of manufacture:

(1) By electrolysis of potassium chloride followed by exposing the resultant potassium to carbon dioxide;

(2) By treating a solution of potassium hydroxide with excess carbon dioxide to produce potassium carbonate;

(3) By treating a solution of potassium hydroxide with carbon dioxide to produce potassium bicarbonate, which is then heated to yield potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 240, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 in food as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; nutrient supplement as defined in § 170.3(o)(20) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

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

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

e. By adding new § 184.1736, to read as follows:

§ 184.1736 Sodium bicarbonate.

(a) Sodium bicarbonate ($NaHCO_3$, CAS Reg. No. 144–55–8) is prepared by treating a sodium carbonate or a sodium carbonate and sodium bicarbonate solution with carbon dioxide. As carbon dioxide is absorbed, a suspension of sodium bicarbonate forms. The slurry is filtered, forming a cake which is washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 278, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

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

f. By adding new § 184.1742, to read as follows:

§ 184.1742 Sodium carbonate.

(a) Sodium carbonate (Na_2CO_3, CAS Reg. No. 497–19–8) is produced (1) From purified trona ore that has been calcined to soda ash; (2) from trona ore calcined to impure soda ash and then purified; or (3) synthesized from limestone by the Solvay process.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 280, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 in food as an antioxidant as defined in § 170.3(o)(3) of this chapter; curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and processing aid as defined in § 170.3(o)(24) of this chapter.

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

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

g. By adding new § 184.1792, to read as follows:

§ 184.1792 Sodium sesquicarbonate.

(a) Sodium sesquicarbonate ($Na_2CO_3.NaHCO_3.2H_2O$, CAS Reg. No. 533-96-0) is prepared by: (1) Partial carbonation of soda ash solution followed by crystallization, centrifugation, and drying; (2) double refining of trona ore, a naturally occurring impure sodium sesquicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 299, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in cream at levels not to exceed current good manufacturing practice. Current good manufacturing practice utilizes a level of the ingredient sufficient to control lactic acid prior to pasteurization and churning of cream into butter.

(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 19, 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. 83-30812 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 79N-0209]

GRAS Status of Potassium Hydroxide and Sodium Hydroxide

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that potassium hydroxide and sodium hydroxide 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 19, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1631 and 184.1763 effective on December 19, 1983.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 22, 1980 (45 FR 11842), FDA published a proposal to affirm that potassium hydroxide and sodium hydroxide 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 27, 1982 (47 FR 37931), in which FDA proposed not to include levels of use and food categories in the GRAS regulations on potassium hydroxide and sodium hydroxide and changed the food grade specifications. The tentative final rule provided an opportunity for public comment on these changes.

One comment was received in response to the agency's tentative final rule on potassium and sodium hydroxides. The comment supported the tentative final rule and the removal of maximum use levels and food categories.

The agency concludes that no changes in the tentative final rule are necessary as a result of this comment. The agency is therefore issuing the tentative final rule 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 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.

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

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing the entry "Sodium hydroxide" from the list of substances.

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entry "Sodium hydroxide" from the list of substances.

§ 182.1631 [Removed]

c. By removing § 182.1631 *Potassium hydroxide.*

§ 182.1763 [Removed]

d. By removing § 182.1763 *Sodium hydroxide.*

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

2. Part 184 is amended:

a. By adding new § 184.1631, to read as follows:

§ 184.1631 Potassium hydroxide.

(a) Potassium hydroxide (KOH, CAS Reg. No. 1310–58–3) is also known as caustic potash, potash lye, and potassa. The empirical formula is KOH. It is a white, highly deliquescent caustic solid, which is marketed in several forms, including pellets, flakes, sticks, lumps, and powders. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available from inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 formulation aid as defined in § 170.3(o)(14) of this chapter; a pH control agent as defined in § 170.3(o)(23) of the chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

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

(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 § 184.1763, to read as follows:

§ 184.1763 Sodium hydroxide.

(a) Sodium hydroxide (NaOH, CAS Reg. No. 1310–73–2) is also known as sodium hydrate, soda lye, caustic soda, white caustic, and lye. The empirical formula is NaOH. Sodium hydroxide is prepared commercially by the electrolysis of sodium chloride solution and also by reacting calcium hydroxide with sodium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 pH control agent as defined in § 170.3(o)(23) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(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 19, 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 26, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30813 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 78N-0372]

GRAS Status of Stearic Acid and Calcium Stearate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that stearic acid and calcium stearate 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 19, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1090 and 184.1229 effective December 19, 1983.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 1, 1983 (48 FR 4486), FDA published a proposal to affirm that stearic acid and calcium stearate are GRAS for use as direct human food ingredients. FDA published this proposal in accordance with its 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 on stearic acid and calcium stearate and the report of the Select Committee on GRAS Substances (the Select Committee) on these substances 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 stearic acid and calcium stearate, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient 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 stearic acid or calcium stearate 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 stearic acid or calcium stearate were submitted in response to the proposal. Therefore, in accordance with the

proposal, any right to assert a prior sanction for use of stearic acid or calcium stearate 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 stearic acid and calcium stearate. Therefore, the agency is issuing the proposal 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 regulation. 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 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).

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

§ 182.70 [Amended]

1. Part 182 is amended in § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing the entry for "Stearic acid."

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

2. Part 184 is amended:

a. By adding new § 184.1090, to read as follows:

§ 184.1090 Stearic acid.

(a) Stearic acid ($C_{18}H_{36}O_2$, CAS Reg. No. 5–11–4) is a white to yellowish white solid. It occurs naturally as a glyceride in tallow and other animal or vegetable fats and oils and is a principal constituent of most commercially hydrogenated fats. It is produced commercially from hydrolyzed tallow derived from edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 313, which is incorporated by reference, and the requirements of § 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St NW., Washington, D.C. 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 flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(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 § 184.1229, to read as follows:

§ 184.1229 Calcium stearate.

(a) Calcium stearate ($Ca[C_{17}H_{35}COO]_2$, CAS Reg. No. 1529–23–0) is the calcium salt of stearic acid derived from edible sources. It is prepared as a white precipitate by mixing calcium chloride and sodium stearate in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 64, which is incorporated by reference, and the requirements of § 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; and a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

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

Effective date. These regulations shall be effective December 16, 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 24, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30800 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket No. 80N-0274]

GRAS Status of Tartaric Acid and Certain Tartrates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Adminstration (FDA) is affirming that

tartaric acid, potassium acid tartrate, sodium tartrate, and sodium potassium tartrate are generally recognized as safe (GRAS) for use as direct human food ingredients. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency.

DATES: Effective December 19, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1077, 184.1099, 184.1801, and 184.1804 effective on December 19, 1983.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 17, 1982 (47 FR 35772), FDA published a proposal to affirm that tartaric acid and certain tartrate salts 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, mutagenic evaluation, teratologic evaluation, and the report of the Select Committee on GRAS Substances (the Select Committee) on tartaric acid and certain tartrate salts 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 tartaric acid and certain tartrates, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient 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 tartaric acid and certain tartrates 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 tartaric acid and certain tartrates were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of tartaric acid and certain tartrates 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 tartaric acid and certain tartrates. The agency is therefore issuing the proposed regulations 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 these regulations. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the 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 (adddress 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

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing "Tartaric acid" from the list of substances.

§§ 182.1077, 182.1099, 182.1804, 182.6099, 182.6801, 182.6804 [Removed]

b. By removing § 182.1077 *Potassium acid tartrate*, § 182.1099 *Tartaric acid*, § 182.1804 *Sodium potassium tartrate*, § 182.6099 *Tartaric acid*, § 182.6801 *Sodium tartrate*, and § 182.6804 *Sodium potassium tartrate*.

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

2. Part 184 is amended:

a. By adding new § 184.1077, to read as follows:

§ 184.1077 Potassium acid tartrate.

(a) Potassium acid tartrate ($C_4H_5KO_6$, CAS Reg. No. 868-14-4) is the potassium acid salt of L-(+)-tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 238, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 in § 170.3(o)(1) of this chapter; an antimicrobial agent as defined in § 170.3(o)(2) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; a leavening agent as defined in § 170.3(o)(17) of this chapter; A pH control agent as defined in § 170.3(o)(23) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; and a surface-active agent as defined in § 170.3(o)(29) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; gelatins and puddings as defined in § 170.3(n)(22) of this chapter; hard candy as defined in § 170.3(n)(25) of this chapter; jams and jellies as defined in § 170.3(n)(28) 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.

b. By adding new § 184.1099, to read as follows:

§ 184.1099 Tartaric acid.

(a) Food grade tartaric acid ($C_4H_6O_6$, CAS Reg. No. 82-69-4) has the L configuration. The L form of tartaric acid is dextrorotatory in solution and is also known as L-(+)-tartaric acid. Tartaric acid occurs as colorless or translucent crystals or as a white, crystalline powder. It is odorless and has an acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Cnemicals Codex, 3d Ed. (1981), P. 320, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 firming agent as defined in § 170.3(o)(10) of this chapter; a flavor enhancer as defined in § 170.3(o)(11) of this chapter; a flavoring agent as defined in § 170.3(o)(12) of this chapter; a humectant as defined in § 170.3(o)(16) of this chapter; and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

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

c. By adding new § 184.1801, to read as follows:

§ 184.1801 Sodium tartrate.

(a) Sodium tartrate ($C_4H_4Na_2O_6.2H_2O$, CAS Reg. No. 868-18-8) is the disodium salt of L-(+)-tartaric acid. It occurs as transparent, colorless, and odorless crystals. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 303, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 emulsifier as defined in § 170.3(o)(8) of this chapter and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in§ 170.3(n)(5) of this chapter; fats and oils as defined in § 170.3(n)(12) of this chapter; and jams and jellies as defined in § 170.3(n)(28) of this chapter.

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

d. By adding new § 184.1804, to read as follows:

§ 184.1804 Sodium potassium tartrate.

(a) Sodium potassium tartrate ($C_4H_4KNaO_6.4H_2O$, CAS Reg. No. 304-59-6) is the sodium potassium salt of L-(+)-tartaric acid and is also called the Rochelle salt. It occurs as colorless crystals or as a white, crystalline powder and has a cooling saline taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 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 emulsifier as defined in § 170.3(o)(8) of this chapter and as a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in § 170.3(n)(5) of this chapter and jams and jellies as defined in § 170.3(n)(28) 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 is effective December 19, 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. 83-30810 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 184

[Docket No. 77N-0039]

GRAS Status of Sodium Alginate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that

sodium alginate is generally recognized as safe (GRAS) as a direct human food ingredient for use in processed fruits and fruit juices. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: December 19, 1983.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 1983 (48 FR 4002), FDA published a proposal to amend the GRAS status of sodium alginate to include its use in processed fruits and fruit juices at a level of 2.0 percent. The proposed amendment was published in response to a comment which noted that FDA had inadvertently omitted this use from its final rule on alginates, which was published July 9, 1982 (47 FR 29946).

No comments were received in response to the agency's proposed amendment to the GRAS affirmation regulation for sodium alginate (21 CFR 184.1724). Therefore, the agency is amending § 184.1724 as proposed. FDA is also making minor editorial changes in the table found in § 184.1724.

The agency has determined pursuant to 21 CFR 25.24 (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 that may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects in 21 CFR Part 184

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

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

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), Part 184 is amended in § 184.1724(c) by revising the table, to read as follows:

§ 184.1724 Sodium alginate.

* * * * *

(c) * * *

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Condiments and relishes, § 170.3(n)(8) of this chapter, except pimento ribbon for stuffed olives	1.0	Texturizer, § 170.3(o)(32) of this chapter, formulation aid § 170.3(o)(14) of this chapter, stabilizer, thickener, § 170.3(o)(28) of this chapter.
Pimento ribbon for stuffed olives	6.0	Do.
Confections and frostings, § 170.3(n)(9) of this chapter.	0.3	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Gelatins and puddings, § 170.3(n)(22) of this chapter.	4.0	Firming agent, § 170.3(o)(10) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.
Hard candy, § 170.3(n)(25) of this chapter	10.0	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	2.0	Formulation aid, § 170.3(o)(14) of this chapter; texturizer, § 170.3(o)(32) of this chapter.
All other food categories	1.0	Emulsifier, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; processing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface active agent, § 170.3(o)(29) of this chapter.

* * * * * * *

Effective date. This regulation is effective December 19, 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 24, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-30811 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address for A. H. Robins Co.

EFFECTIVE DATE: November 18, 1983.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Bureau of Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: A. H. Robins Co., 1405 Cummings Dr., P.O. Box 26609, Richmond, VA 23261, has informed FDA of a change of sponsor name and address. This is an administrative change which does not in any other way affect the approval of the firm's NADA's. The agency is amending the regulations to reflect the change.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.