

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the food additive regulations to provide for the safe use of an octyltin stabilizer in polyvinyl chloride and vinyl chloride copolymers intended for use in contact with food. This document corrects two errors in 21 CFR 178.2650 (a)(4) and (b)(1)(ii).

EFFECTIVE DATE: September 21, 1983.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204. 202-472-5690.

SUPPLEMENTARY INFORMATION: In FR Doc. 83-11192 in the Federal Register of Wednesday, September 21, 1983, the following corrections are made in § 178.2650 *Octyltin stabilizers in vinyl chloride plastics* on page 42972 in the third column:

1. In paragraph (a)(4), third column, eleventh line, the words "percent by weight total alkyltin" are changed to read "percent by weight total of other eight (8) carbon isomeric alkyltin".
2. In paragraph (b)(1)(ii), second line, the words "0.5 per" are changed to read "0.5 parts per".

Dated: October 14, 1983.
Richard J. Ronk,
Acting Director, Bureau of Foods.
[FR Doc. 83-30367 Filed 11-9-83; 8:43 am]
BILLING CODE 4150-01-M

21 CFR Parts 182 and 184

[Docket No. 81N-0280]

Gras Status of Malt Syrup (Malt Extract)

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

SUMMARY: The Food and Drug Administration (FDA) is affirming that malt syrup (malt extract) 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.

EFFECTIVE DATE: December 12, 1983.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 6, 1982 (47 FR 34158), FDA published a proposal to affirm that malt syrup (malt extract) 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 on malt syrup (malt extract) and the report of the Select Committee on GRAS Substances (the Select Committee) on malt syrup (malt extract) 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 malt syrup (malt extract), FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of the prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of malt syrup (malt extract) 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 malt syrup (malt extract) were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of malt syrup (malt extract) 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 malt syrup (malt extract). The agency is therefore issuing the proposal as a final rule with a minor editorial change.

In the proposal, FDA stated that it would work with the Committee on Codex Specifications (now known as the Committee on Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for malt syrup (malt extract) used as a direct food ingredient and would incorporate those specifications into the regulation when they were developed. To date, however, work on the

specifications is still incomplete. Until the specifications are developed, malt syrup (malt extract) for direct food uses must comply with the description in § 184.1445 and be of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

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.

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

§ 182.20 [Amended]

1. Section 182.20 *Essential oils, oleoresins (solvent-free), and natural extractives (including distillates)* is amended by removing the entry "Malt (extract)" from the list of substances.

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

2. Part 184 is amended by adding new § 184.1445, to read as follows:

§ 184.1445 Malt syrup (malt extract).

(a) Malt is the product of barley (*Hordeum vulgare* L.) germinated under controlled conditions. Malt syrup and malt extract are interchangeable terms for a viscous concentrate of water extract of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt extract) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) FDA is developing food-grade specifications for malt syrup (malt extract) in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(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 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 12, 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. 83-30115 Filed 11-9-83; 8:45 am]

BILLING CODE 4180-01-M

21 CFR Parts 182 and 184

[Docket No. 80G-0306]

GRAS Status of Potassium Chloride

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

SUMMARY: The Food and Drug Administration (FDA) is affirming that potassium chloride 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 12, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1622 effective on December 12, 1983.

FOR FURTHER INFORMATION CONTACT: John Dawson, 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 August 20, 1982 (47 FR 36440), FDA published a proposal to affirm that potassium chloride 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 on potassium chloride and the report of the Select Committee on GRAS Substances (the Select Committee) on potassium chloride 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 potassium chloride, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 8, 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 potassium chloride 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 potassium chloride were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of potassium chloride 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 potassium chloride. The agency is therefore issuing the proposal as a final rule with a minor editorial 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 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

1. Part 182 is amended:

- a. In § 182.5622 by revising paragraph (b), to read as follows:

§ 182.5622 Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with current good manufacturing practice. Preparations containing amounts equal to or greater than 100 milligrams of potassium per tablet or capsule, or 20 milligrams of potassium per milliliter, are drugs subject to the provisions of § 201.306 of this chapter.

§ 182.8622 [Removed]

- b. By removing § 182.8622 Potassium chloride.

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

2. Part 184 is amended by adding new § 184.1622, to read as follows:

§ 184.1622 Potassium chloride.

(a) Potassium chloride (KCl, CAS Reg. No. 7447-40-7) is a white, odorless solid prepared from source minerals by fractional crystallization or flotation. It is soluble in water and glycerol and has a saline taste at low concentration levels.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 241, 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 flavor enhancer as defined in § 170.3(o)(11) of this chapter; as a flavoring agent as defined in § 170.3(o)(12) of this chapter; as a nutrient supplement as defined in § 170.3(o)(20) of this chapter; as a pH control agent as defined in § 170.3(o)(23) of this chapter; and as a stabilizer or 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. Potassium chloride may 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.

Effective date. This regulation shall be effective December 12, 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 21, 1983.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30113 Filed 11-9-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 79P-0404]

GRAS Status of Pyridoxine Hydrochloride

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

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

DATE: Effective December 12, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1676 effective on December 12, 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 October 8, 1982 (47 FR 44572), FDA published a proposal to affirm that pyridoxine hydrochloride 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 on pyridoxine hydrochloride and the report of the Select Committee on GRAS Substances (the Select Committee) on pyridoxine hydrochloride 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 pyridoxine hydrochloride, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of pyridoxine hydrochloride 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 pyridoxine hydrochloride were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of pyridoxine hydrochloride 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 pyridoxine hydrochloride. The agency is therefore issuing the proposed

regulation as a final rule with a minor editorial 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 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

§ 182.8676 [Removed]

1. Part 182 is amended by removing § 182.8676 *Pyridoxine hydrochloride*.

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

2. Part 184 is amended by adding new § 184.1676, to read as follows:

§ 184.1676 *Pyridoxine hydrochloride*.

(a) *Pyridoxine hydrochloride* ($C_8H_{11}NO_3 \cdot HCl$, CAS Reg. No. 58-56-0) is the chemical 3-hydroxy-4,5-dihydroxymethyl-2-methylpyridine hydrochloride that is prepared by chemical synthesis.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 260, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

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

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

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; breakfast cereals as defined in § 170.3(n)(4) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; meat products as defined in § 170.3(n)(29) of this chapter; milk products as defined in § 170.3(n)(31) of this chapter; plant protein products as defined in § 170.3(n)(33) of this chapter; and snack foods as defined in § 170.3(n)(37) of this chapter. *Pyridoxine hydrochloride* may 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.

Effective date. This regulation shall be effective December 12, 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. 83-30116 Filed 11-9-83; 8:45 am)

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 80N-0147]

GRAS Status of Urea

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

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

EFFECTIVE DATE: December 12, 1983.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 13, 1982 (47 FR 35247), FDA published a proposal to affirm that urea 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 on urea and the report of the Select Committee on GRAS Substances (the Select Committee) on urea 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 urea, FDA gave public notice that it was unaware of any prior-sanctioned food 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 8, 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 urea 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 urea were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of urea under conditions different from those set forth in this final rule has been waived.

One comment, from a producer of urea, was received in response to the agency's proposal. The comment objected to the use of the word "crystalline" in the regulation to describe urea. The comment stated that the term "crystalline" results in an unnecessarily restrictive definition of urea because there are several forms of urea, including granular and prilled, that are also commonly used.

The agency has reviewed this comment and disagrees that the use of the term "crystalline" in the definition of urea is too restrictive and would exclude other physical forms of the substance. However, to avoid confusion the regulation has been modified to exclude the term "crystalline." The agency is therefore issuing the proposed regulation as a final rule with minor editorial changes.

In the proposal, FDA stated that it would work with the Committee on Codex Specifications (now known as the Committee on Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for urea used as a direct human food ingredient and would incorporate those specifications into the regulation when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, urea for direct food uses must comply with the description in § 184.1923 and be of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

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 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.

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 for "Urea."

§ 182.90 [Amended]

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

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

2. Part 184 is amended by adding new § 184.1923, to read as follows:

§ 184.1923 Urea.

(a) Urea ($\text{CO}(\text{NH}_2)_2$, CAS Reg. No. 57-13-6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(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 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 fermentation aid in the production of alcoholic beverages.

(2) The ingredient is used in alcoholic beverages as defined in § 170.3(n)(2) 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 12, 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 21, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30118 Filed 11-9-83; 8:45 am]

BILLING CODE 4160-50-M

21 CFR Part 184

[Docket No. 82G-0197]

GRAS Status of Candelilla Wax

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

SUMMARY: The Food and Drug Administration (FDA) is affirming that candelilla 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 12, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1976 effective on December 12, 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 17, 1982 (47 FR 35776), FDA published a proposal to affirm that candelilla 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 on candelilla wax and the report of the Select Committee on GRAS Substances (the Select Committee) on candelilla wax are available for public review at 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 candelilla wax, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of the prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of candelilla wax 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 candelilla wax were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of candelilla wax conditions different from those set forth in this final rule has been waived.

No comments were received in response to the proposal on candelilla wax. 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 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 in 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), Part 184 is amended by adding new § 184.1976, to read as follows:

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

§ 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006-44-8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, 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 lubricant as defined in § 170.3(o)(18) of this chapter and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in § 170.3(n)(6) of this chapter and in hard candy as defined in § 170.3(n)(25) 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 12, 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 21, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30147 Filed 11-9-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 80N-0245]

GRAS Status of Nickel

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

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

EFFECTIVE DATE: December 12, 1983.

FOR FURTHER INFORMATION CONTACT: John Dawson, 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 October 19, 1982 (47 FR 46545), FDA published a proposal to affirm that nickel 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 on nickel and the report of the Select Committee on GRAS Substances (the Select Committee) on nickel are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-82, 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 nickel, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of nickel 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 nickel were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of nickel under conditions different from those set forth in this final rule have been waived.

No comments were received in response to the agency's proposal on nickel. The agency is therefore issuing the proposal as a final rule without change.

In the proposal, FDA stated that it would work with the Committee on

Codex Specifications (now known as the Committee on Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for nickel used as a direct food ingredient and would incorporate those specifications into the regulation when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, nickel for direct food uses must comply with the description in § 184.1537 and be of food-grade purity (21 CFR 182.1(b)(3) and 170.30(h)(1)).

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 in 21 CFR Part 184

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

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 by adding new § 184.1537, to read as follows:

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

§ 184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440-02-0) is obtained from nickel ore by transforming it to nickel sulfide (Ni_3S_2). The sulfide is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give elemental nickel.

(b) The Food and Drug Administration is developing food-grade specifications for nickel in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(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 catalyst as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in § 170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

(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 12, 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. 83-30114 Filed 11-9-83; 8:45 am]

BILLING CODE 4160-01-M