

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. 84, 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. 83-30000 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

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 Administration (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 (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:

§ 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 (+)-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 Chemicals 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 ($C_4H_4Na_2O_6 \cdot 2H_2O$, 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 ($C_4H_4KNaO_6 \cdot 4H_2O$, 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. 83-30610 Filed 11-17-83; 8:45 am]

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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.
Gelatin and puddings, § 170.3(n)(22) of this chapter	4.0	Firming agent, § 170.3(o)(10) of this chapter; flavor adjunct, § 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 adjunct, § 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 23281, 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.

PART 510—NEW ANIMAL DRUGS**§ 510.600 [Amended]**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the entry for "A. H. Robins Co., Research Laboratories" in paragraph (c)(1) and in the entry for "000031" in paragraph (c)(2) by changing the entry for the firm name and address to read "A. H. Robins Co., 1405 Cummings Dr., P.O. Box 26609, Richmond, VA 23261."

Effective date, November 18, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: November 14, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-31105 Filed 11-17-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE**Office of the Attorney General****28 CFR Part 0**

(Civil Division Directive No. 158-83)

Further Revision of Civil Division Directive No. 145-81

AGENCY: Justice Department.

ACTION: Final rule.

SUMMARY: This document amends Civil Division Directive No. 145-81, as it appears in 46 FR 52352 (Oct. 27, 1981), and as revised by Directive No. 151-82, 47 FR 21533 (May 19, 1982). These changes reflect transfer of the Consumer Affairs Section from the Antitrust Division to the Civil Division and transfer of certain civil litigation arising under the the Immigration and Nationality Act and related laws from the Criminal Division to the Civil Division, pursuant to DOJ Order No. 1002-83, 48 FR 9522 (March 7, 1983).

EFFECTIVE DATE: February 23, 1984.

FOR FURTHER INFORMATION CONTACT:

Robert N. Ford, Civil Division, Room 3137, 9th & Pennsylvania Avenue, NW., Washington, D.C. 20530, Telephone No. (202) 633-3309. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The requirements of Executive Order No. 12291 (Federal Regulation) do not apply to this directive because it deals with

agency management and is therefore exempt under section 1(a)(3) of that Order. Additionally, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, do not apply because this directive is not a "rule" under section 601(2).

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Claims, Government employees organization and functions (Government agencies).

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

By the authority vested in me as Assistant Attorney General, Civil Division, by 28 CFR 0.168, Civil Division Directive No. 145-81 (Appendix to Subpart Y of Part 0, Title 28, Code of Federal Regulations) is amended as follows:

Appendix to Subpart Y [Amended]**1. Section 1(b) is revised to read:**

(b) Delegation to Branch Directors, the Director of the Appellate Staff, the Chief of the Judgment Enforcement Unit, the Director of the Office of Foreign Litigation, the Director of the Office of Immigration Litigation, and the Director of the Office of Consumer Litigation. Subject to the limitations imposed by paragraph (d) of this section, Branch Directors, the Director of the Appellate Staff, the Chief of the Judgment Enforcement Unit, the Director of the Office of Foreign Litigation, the Director of the Office of Immigration Litigation, and the Director of the Office of Consumer Litigation are hereby authorized, with respect to matters assigned to their respective components, to reject any offer in compromise and to accept offers in compromise and close claims or cases in the manner and to the same extent as Deputy Assistant Attorneys General, except that Branch Directors, the Director of the Appellate Staff, the Chief of the Judgment Enforcement Unit, the Director of the Office of Foreign Litigation, the Director of the Office of Immigration Litigation, and the Director of the Office of Consumer Litigation cannot accept or reject any offers in compromise of, or settle administratively any claim or case against the United States where the principal amount to be paid by the United States exceeds \$150,000. Nor can these Civil Division officials close (other than by compromise or by entry of judgment), any claim or case on behalf of the United States where the gross amount involved exceeds \$150,000 or accept or reject any offers in compromise of any such claim or case in which the difference between the gross amount of the original claim and the proposed settlement exceeds \$150,000 or 10 percent of the original claim, whichever is greater. Branch Directors, the Chief of the Judgment Enforcement Unit, the Director of the Office of Foreign Litigation, the Director of the Office of Immigration Litigation, and

the Director of the Office of Consumer Litigation are further authorized to file suits, counterclaims, and cross-claims, or to take any other action necessary to protect the interests of the United States in all nonmonetary cases, in all routine loan collection and foreclosure cases, and in other monetary claims or cases where the gross amount of the claim does not exceed \$150,000.

2. Section 1((c)(2) is revised to read:

(c)(2) Accept or reject offers to compromise cases and close claims which have been directly referred or delegated to them by the Civil Division, as set forth in sections 4 (a) and (b) of this directive, in the same manner and to the same extent as Branch and Office Directors, except that United States Attorneys and Attorneys-in-Charge of field offices cannot accept or reject any offers in compromise of any claim or case against the United States where the principal amount of the proposed settlement exceeds \$100,000. Nor can United States Attorneys or Attorneys-in-Charge of field offices close (other than by compromise or by entry of judgment) any claim or case on behalf of the United States where the gross amount involved exceeds \$100,000, or accept or reject any offers in compromise of any such claim or case in which the difference between the gross amount of the original claim and the proposed settlement exceeds \$100,000 or 10 percent of the original claim, whichever is greater. United States Attorneys may redelegate this authority to Assistant United States Attorneys who supervise other Assistant United States Attorneys who handle civil litigation.

3. Section 4(c) is amended by adding new subparagraphs (8) and (9) which are to read:

(8) Criminal proceedings arising under statutes enforced by the Food and Drug Administration, the Consumer Product Safety Commission, the Federal Trade Commission, and the National Highway Traffic Safety Administration (relating to odometer tampering), except as determined by the Director of the Office of Consumer Litigation. (c) . . .

(9) Nonmonetary civil cases, including injunction suits, declaratory judgment actions, and applications for inspection warrants, and cases seeking civil penalties, arising under statutes enforced by the Food and Drug Administration, the Consumer Product Safety Commission, the Federal Trade Commission, and the National Highway Traffic Safety Administration (relating to odometer tampering), except as determined by the Director of the Office of Consumer Litigation.

(5 U.S.C. 301; 28 U.S.C. 509 and 510)

J. Paul McGrath

Assistant Attorney General.

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