

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 7, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective April 6, 1979.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: April 2, 1979.

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

[Docket No. 77F-0256]

[FR Doc. 79-10715 Filed 4-5-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 182, 184

Malic Acid; GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that malic acid 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 being conducted by the agency.

EFFECTIVE DATE: May 7, 1979.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St., SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 30, 1977 (42 FR 43644), a proposal was published to affirm that malic acid is generally recognized as safe 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 malic acid, reports of the mutagenic and teratogenic tests for the ingredient, and the report of the Select Committee on GRAS Substances (the Select Committee) are available for public review in the office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 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 malic acid, the Commissioner gave public notice that he was unaware of any prior-sanctioned food ingredient uses for this ingredient, other than for the proposed conditions of use, and advised persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, to submit proof of those sanctions so that the safety of the prior-sanctioned uses could be determined. The Commissioner proposed to approve prior-sanctioned uses of malic acid in appropriate regulations under Part 181 (21 CFR Part 181), if the prior-sanctioned use could be affirmed as safe on the basis of information and data then available to him.

The Commissioner 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 malic acid were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of malic acid under conditions different from those set forth in this regulation has been waived.

Four comments were received in response to the proposal. All the comments concerned the maximum levels of malic acid in confectioners' products. A summary of the comments and the Commissioner's response follows.

The comments expressed the collective view that the proposed maximum levels for malic acid in hard candy (0.9 percent), powdered candy (0.7 percent), and chewing gum (0.7 percent) were too low relative to current manufacturing practice. Two comments recommended elevation of the maximum level in hard candy to 6.9 percent. Two other comments recommended separation of "powdered candy" and "chewing gum" from the "all other foods" category and requested maximum level of 3.0 percent malic acid for both.

The Commissioner has carefully considered the requested modifications in the maximum levels for malic acid in confectioners' products. The Commissioner recognizes that the 1971 National Academy of Sciences/National Research Council (NAS/NRC) survey upon which the proposed maximum usage levels were based, was not comprehensive and, in fact, probably represented only 60 percent of food ingredient users in the United States. The Commissioner has determined that the maximum usage levels for malic acid recommended in the comments for certain confectioners' products represent current good manufacturing practice for those products. Although the newly reported levels of use for malic acid are higher than the levels reported in the 1971 survey and the levels upon which the Select Committee based its safety evaluation, the Commissioner concludes that there are adequate safety data to support higher levels of use in these limited food categories. The maximum usage levels proposed in the comments are, therefore, included in this regulation. It is emphasized, however, that these higher usage levels are not an authorization for use of malic acid at any level higher than is necessary to achieve the intended effect in a specific food.

In accordance with the Commissioner's conclusion, the following regulation has been amended to reflect current good manufacturing practice. The maximum level of malic acid in hard candy is raised to 6.9 percent. Chewing gum is separated from other food categories and has a maximum malic acid level of 3.0 percent. Powdered candy, which is included in the definition of soft candy in 21 CFR

170.3(n)(38), has a maximum malic acid level of 3.0 percent.

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 (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. In Part 182, as follows:

§ 182.60 [Amended]

a. In § 182.60 *Synthetic flavoring substances and adjuvants*, by deleting the entry for "1-Malic acid."

§ 182.1069 [Deleted]

b. By deleting § 182.1069 *Malic acid*.

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

2. In Part 184, by adding new § 184.1069 to read as follows:

§ 184.1069 Malic acid.

(a) Malic acid ($C_4H_6O_5$, CAS Reg. No. of L-form 97-67-6, CAS Reg. No. of DL-form 617-48-1) is the common name for 1-hydroxy-1, 2-ethanedicarboxylic acid. L (+) malic acid, referred to as L-malic acid, occurs naturally in various foods. Racemic DL-malic acid does not occur naturally. It is made commercially by hydration of fumaric acid or maleic acid.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 2d Ed. (1972), as amended by the Second Supplement (1975)¹ which is incorporated by reference.

(c) The ingredients are used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter, flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter, and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredients are used in food, except baby food, at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 3.4 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; 3.0 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 0.8 percent for gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter; 6.9 percent for hard candy as defined in

§ 170.3(n)(25) of this chapter; 2.6 percent for jams and jellies as defined in § 170.3(n)(28) of this chapter; 3.5 percent for processed fruits and fruit juices as defined in § 170.3(n)(35) of this chapter; 3.0 percent for soft candy as defined in § 170.3(n)(38) of this chapter; and 0.7 percent for all other food categories.

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

Effective date. This regulation shall be effective May 7, 1979.

(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: March 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference was approved by the Director of the Office of the Federal Register on June 20, 1977 and is on file at the Federal Register Library.

[Docket No. 77N-0178]

[FR Doc. 79-10305 Filed 4-5-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 182, 184

Succinic Acid; GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule affirms that succinic acid 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 being conducted by the agency.

EFFECTIVE DATE: May 7, 1979.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 3, 1978 (43 FR 4635), The Food and Drug Administration (FDA) proposed to affirm that succinic acid is GRAS for use as a direct human food ingredient. The proposal was based on safety information developed by the Select Committee on GRAS Substances (the Select Committee) and was published in accord with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

Under § 170.35 (21 CFR 170.35), relating to the affirmation of GRAS food ingredients, copies of the scientific literature review on succinic acid, data

¹ Copies may be obtained from: National Academy of Sciences, 2101 Constitution Ave. NW., Washington, D.C. 20037.

on a mutagenic evaluation, and the report of the Select Committee have been made available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Copies of the documents have also been made 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 succinic acid, the Commissioner of Food and Drugs gave public notice that he was unaware of any prior-sanctioned food ingredient use 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 prior to September 6, 1958, were given notice to submit proof of such a sanction so that the safety of prior-sanctioned uses could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of succinic acid approved by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), provided the prior-sanctioned use could be affirmed as safe on the basis of data now available to the Commissioner. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert the sanction at any future time.

No reports of a prior-sanctioned use for succinic acid were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of succinic acid under conditions different from those set forth in this regulation has been waived.

No comments were received in response to the Commissioner's proposal and supporting data and information on succinic acid. The Commissioner therefore concludes that no change in the proposal to affirm the GRAS status of succinic acid is warranted. Accordingly, it is being promulgated without change.

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 (21 CFR 5.1), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.1091 [Deleted]

1. In Part 182 by deleting § 182.1091 *Succinic acid*.

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

2. In Part 184 by adding new § 184.1091 to read as follows:

§ 184.1091 Succinic acid.

(a) Succinic acid ($C_4H_6O_4$, CAS Reg. No. 110-15-6), also referred to as amber acid and ethylenesuccinic acid, is the chemical 1,4-butanedioic acid. It is commercially prepared by hydrogenation of maleic or fumaric acid. It can also be produced by aqueous alkali or acid hydrolysis of succinonitrile.

(b) The ingredient meets specifications of the Food Chemicals Codex, 2d Ed. (1972), which is incorporated by reference.¹

(c) The ingredient is used as a flavor enhancer as defined in § 170.3(o)(11) of this chapter and pH control agent as defined in § 170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.084 percent in condiments and relishes as defined in § 170.3(n)(8) of this chapter and 0.0061 percent in meat products as defined in § 170.3(n)(29) of this chapter.

(e) 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 May 7, 1979.

(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: March 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporation by reference was approved on July 10, 1973 by the Director of the Office of the Federal Register and is on file in the Federal Register Library.

[Docket No. 77N-0259]

[FR Doc. 79-10308 Filed 4-5-79; 8:45 am]

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¹ Copies may be obtained from: The National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20037.

21 CFR Part 201

Drugs: Information Commonly Known; Revocation of Labeling Exemption

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the drug labeling regulations to revoke provisions that exempt certain prescription drugs from the requirement that the dispensing package contain full disclosure labeling (i.e., a package insert). The agency is taking this action because it has concluded that the exemptions are not warranted and that full disclosure labeling is necessary for the safe and effective use of prescription drugs.

EFFECTIVE DATE: October 3, 1979.

FOR FURTHER INFORMATION CONTACT: Michael C. McGrane, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 27, 1977 (42 FR 27263), FDA proposed to revoke the provision in § 201.100(c)(2) (21 CFR 201.100(c)(2)) that permits full disclosure labeling (the package insert) to be omitted from the dispensing package of certain prescription drugs and to revoke § 201.160 (21 CFR 201.160), which lists the drugs to which the exemption has applied. Interested persons were given to July 26, 1977, to submit comments on the proposal.

Eight comments were received on the proposal, six from manufacturers of drug products subject to the regulations and two from trade associations. A summary of the comments and the agency's responses to them follows:

1. Three comments objected to the blanket revocation of the exemption from the package insert requirement for the drugs listed in § 201.160. The comments contended that each of the exempted drugs should be examined individually to determine whether its continued exemption from the package insert requirement poses a potential hazard to the public health or whether a specific benefit can be shown to flow from the future use of a package insert with each of the drugs. One comment argued that the proposed revocation of the exemption is based on the agency's opinion about, and experience with, other drugs, but only the identification of a specific risk from the exemption or a specific benefit that will result from its revocation would justify revoking the exemption. Another comment argued