aspartame consumption is not harmful because methanol is a component of fruit juices and a few vegetables; the objector claims that this reasoning is faulty because methanol in these natural products is safely bound by pectin and is always accompanied by ethanol, which is claimed to block any damaging effects of methanol. In support of this objection, the objector filed an outline of the toxicity of methanol, including the quantity ingested from the degradation of aspartame and a list of the breakdown products of aspartame.

FDA has considered this third objection and has determined, as set out below, that it does not provide a basis for reconsideration or alteration of the final rules in question.

First, FDA has previously considered the possible effects of DKP from metabolism of aspartame (48 FR 31376 at 31380, July 8, 1983; 49 FR 6672 at 6677, February 22, 1984). FDA agrees that DKP concentration may increase if aspartame is stored under abusive conditions. However, based on well-conducted chronic bioassays in two rodent species, FDA previously concluded that the acceptable daily intake of DKP exceeds any dietary exposure that is likely to result from aspartame consumption (48 FR 52899 at 52901, November 23, 1983). No objector filed any data or information to support its assertion to the contrary. In such circumstances, there is no basis to reevaluate the final rules at issue.

Second, FDA has also previously considered the effect, if any, that methanol has on the safety of aspartame consumption. FDA determined that the amount of methanol due to exposure to aspartame is well below levels that produce the earliest signs of methanol toxicity (49 FR 6672 at 6677, February 22, 1984). Furthermore, the levels of methanol from ingesting aspartame is the same magnitude as that presented by other food sources, such as fruit juices and tomatoes; those levels of methanol are easily eliminated or metabolized by the body. No objector provided any new data or information to contradict FDA's previous evaluation of this issue. Accordingly, FDA is overruling this objection.

D. Absence of Warning Labels on Aspartame

A fourth objection questioned the absence of a label warning pregnant women to avoid products containing aspartame and asserted that aspartame causes fetal damage and mental retardation. This objection also questioned the usefulness of the phenylketonuria labeling for products containing aspartame and appeared to imply that certain carriers of the PKU gene are at risk from consumption of aspartame. No objector provided any specific data or information to support the claim that pregnant women cannot safely consume aspartame or that PKU gene carriers are at risk from consumption of aspartame.

In responding above to the ACSN request for a hearing on these same issues, FDA noted that the agency has addressed both issues in prior administrative proceedings on aspartame and that in the absence of new data or information, no hearing need be held. Likewise, in the absence of new data or information, there is no basis for reconsideration or alteration of the final rules at issue here. Therefore, FDA is overruling this fourth objection.

V. Conclusion

As set out above, FDA concludes that no new issues or reliable evidence have been presented to support the objections to the final rules providing for the use of aspartame in frozen desserts and frozen frostings, toppings, and fillings. Furthermore, when analyzed according to the proper standards, ACSN has not justified a hearing on its objections to the final rules.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Schiffman et al., New England Journal of Medicine, 317:1181–1185, 1989.

2. Letter dated November 21, 1986, from John M. Taylor to James S. Turner.

Dated: January 24, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92–2235 Filed 1–29–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 172

[Docket No. 87F–0277]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame as a sweetener in malt beverages of less than 7 percent ethanol by volume and containing fruit juice. This action is in response to a petition filed by The Stroh Brewery Co.

DATES: Effective January 30, 1992; written objections and requests for a hearing by March 2, 1992.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF–333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9528.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 14, 1987 (52 FR 38144), FDA announced that a food additive petition (FAP 7A4029) had been filed by the Stroh Brewery Co., 100 River Pl., Detroit, MI 48207–4291, proposing that § 172.804 Aspartame (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in malt beverages of less than 7 percent ethanol by volume and containing fruit juice.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in 21 CFR 172.804(c) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 2, 1992 file with

the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. Section 172.804 is amended by adding new paragraph (c)(22) to read as follows.

§ 172.804 Aspartame.

* * * * *

(c) * * *

(22) Malt beverages of less than 7 percent ethanol by volume and containing fruit juice.

* * * * *

Dated: January 24, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92-2236 Filed 1-29-92; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 172

[Docket No. 83F-0262]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame as a sweetener available to consumers in bulk package form. This action is in response to a petition filed by the Searle Research and Development Division of G.D. Searle & Co. (now the NutraSweet Co.).

DATES: Effective January 30, 1992; written objections and requests for a hearing by March 2, 1992.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9528.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 8, 1983 (48 FR 40562, FDA announced that a food additive petition (FAP 3A3744) had been filed by the Searle Research and Development Division of G.D. Searle & Co. (now the NutraSweet Co., Box 1111, 4711 Golf Rd., Skokie, IL 60076) proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener available to consumers in bulk package form.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in § 172.804(c)(1) and (e) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 2, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. Section 172.804 is amended by revising paragraph (c)(1) and by adding paragraph (e)(4) to read as follows:

§ 172.804 Aspartame.

* * * * *

(c) * * *

(1) Dry, free-flowing sugar substitutes for table use (not to include use in cooking) in package units not exceeding the sweetening equivalent of 1 pound of sugar.

* * * * *

(e) * * *

(4) Packages of the dry, free-flowing additive shall prominently display the sweetening equivalence in teaspoons of sugar.

* * * * *

Dated: January 24, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92-2237 Filed 1-29-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 172

[Docket No. 88F-0007]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration IFDA) is amending the food additive regulations to provide for the safe use of aspartame as a sweetener in hot and instant cereals. This action is in response to a petition filed by the NutraSweet Co.

DATES: Effective January 30, 1992; written objections and requests for a hearing by March 2, 1992.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9528.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 11, 1988 (53 FR 4075), FDA announced that a food additive petition (FAP 8A4055) had been filed by the NutraSweet Co., 4711 Golf Rd., Skokie, IL 60076, proposing that § 172.804 Aspartame (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in hot and instant cereals.

Aspartame is an approved sweetener for use in cold breakfast cereals under § 172.804(c)(3). The requested amendment will remove the restrictions on temperature and permit the use of aspartame in hot and instant cereals. FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in § 172.804(c)(3) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 2, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. Section 172.804 is amended by revising paragraph (c)(3) to read as follows:

§ 172.804 Aspartame.

* * * * *

(c) * * *

(3) Breakfast cereals.

* * * * *

Dated: January 24, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92-2238 Filed 1-29-92, 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 172

[Docket No. 89F-0127]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame in refrigerated ready-to-serve puddings and fillings. This action is in response to a petition filed by General Foods USA.

DATES: Effective January 30, 1992; written objections and request for a hearing by March 2, 1992.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9528.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register**