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Part V

# Department of Health and Human Services

Food and Drug Administration

21 CFR Part 172

Aspartame; Denial of Request for Hearing on Final Rules; Food Additives Permitted for Direct Human Consumption; Final Rules

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 172**

**[Docket Nos. 87F-0240 and 85F-0346]**

## Aspartame; Denial of Request for Hearing on Final Rules

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule; denial of request for hearing and response to objections.

**SUMMARY:** The Food and Drug Administration (FDA) is denying a request for a hearing on the final rules that amended the food additive regulations to authorize the use of aspartame as a sweetener in frozen dairy and nondairy frostings, toppings, and fillings and in frozen, ready-to-thaw-and-eat cheesecakes, fruit, and fruit toppings. After reviewing the objections to the two final rules and the request for a hearing, FDA has concluded that no genuine issues of material fact have been raised that would justify a hearing. In addition, FDA is overruling other objections to the final rule for which there were no hearing requests because the agency has addressed similar objections in prior administrative proceedings concerning aspartame.

**FOR FURTHER INFORMATION CONTACT:** Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9528.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of June 2, 1989 (54 FR 23646 through 23647), FDA issued final rules that amended § 172.804(c) (21 CFR 172.804) of the food additive regulations by adding new paragraphs (c)(19) and (c)(20). Section 172.804(c)(19) authorizes the use of aspartame as a sweetener in frozen ready-to-thaw-and-eat cheesecakes, fruit, and fruit toppings. This rule responded to a petition filed by Foodways National, Inc. Section 172.804(c)(20) authorizes the use of aspartame as a sweetener in frozen dairy and nondairy frostings, toppings, and fillings. This rule responded to a petition filed by Foodways National, Inc., and the NutraSweet Co.

In accordance with 21 U.S.C. 348(f), four consumers and one consumer group filed objections to the final rules for aspartame. The aspartame Consumer Safety Network (ACSN), the consumer group, also requested a hearing on its objections. The agency's response to each objection and the request for a hearing is provided below.

### II. Standard for Granting a Hearing

The Criteria for deciding whether to grant or deny a hearing are stated in 21 CFR 12.24(b). The regulation states that a hearing will be granted when the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 314.300, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing, are met.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214-215 (1980), *reh. den.*, 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-621 (1973). An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. *Georgia Pacific Corp.* v. *U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Ass'n* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971). Stated another way, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." *Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. See *Citizens for Allegan Country, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality are validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

> The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.
>
> *Retail Clerks Union, Local 1401, R.C.I.A.* v. *NLRB*, 463 F. 2d 316, 322 (DC Cir. 1972). (See *Costle* v. *Pacific Legal Foundation, supra* at 1106; See also *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F. 2d 804 (DC Cir. 1966)).

### III. Analysis of Request for Hearing

The ACSN requested that FDA convene a public hearing to receive and evaluate evidence relevant to its objections on four issues. These four issues are: That an aspartame double blind challenge test (Ref. 1) is erroneous; that pilots have lost their medical

certification to fly due to adverse reactions resulting from their consumption of aspartame; that the labeling of aspartame products will not protect individuals with phenylketonuria (PKU), or other sensitive individuals, when these products are served in the home and other social settings; and that pregnant patients are not being warned that aspartame consumption during pregnancy can cause mental retardation and other birth defects.

*A. Adverse Reactions to Aspartame*

ACSN's first objection challenged the reliability of a double blind test (Ref. 1) reporting that aspartame is unlikely to produce headaches at any greater rate than placebo and implicitly asserted that aspartame causes a wide range of adverse reactions in consumers. In support of this objection, ACSN submitted three letters, published in the New England Journal of Medicine, which reported deficiencies in the study's experimental design. In addition, ACSN submitted news articles, as well as some physician case reports, reporting that some consumers develop headaches after consuming aspartame-containing products.

The study in question was performed by Schiffman, et al., at Duke University. The study was a double blind crossover design in which the investigators administered capsules containing aspartame, at a dosage of 30 milligrams per kilogram of body weight, to 40 human subjects, most of whom had a family or personal history of allergic reactions. In addition, each of the test subjects had previously reported suffering a headache within 24 hours of ingesting aspartame. Thirty-five percent of the subjects reported headaches after taking aspartame, while 45 percent reported headaches after a placebo. No other reactions occurred. The investigators concluded that the study demonstrated that a patient ingesting aspartame is no more likely to suffer a headache than when receiving a placebo.

FDA is denying ACSN's first objection for the following reasons. First, the results of the study by Schiffman, et al., are consistent with the agency's conclusion that aspartame is safe. FDA did not rely upon this study, however, as the basis (or as part of the basis) for the agency's safety determination. Thus, even if the study must be disregarded because it is flawed as ACSN has alleged, this will not alter the foundation underlying FDA's conclusion that aspartame is safe. Therefore, establishment of ACSN's claims of design deficiency would not require the revocation of the aspartame regulations in question. Accordingly, FDA is overruling ACSN's first objection and denying its hearing request on this issue. 21 CFR 12.24(b)(4).

Second, FDA is overruling ACSN's first objection and denying the hearing request to the extent that the objection asserts that aspartame causes a wide range of adverse reactions. The data ACSN filed in support of its hearing request on this issue were in the form of physician case reports and individual testimonials. In previous proceedings on aspartame in November 1986, in which the agency denied a petition of the Community Nutrition Institute (CNI) to revoke all uses of aspartame (Ref. 2), FDA evaluated the use of individual complaints and case reports to determine whether a causal link exists between aspartame consumption and alleged adverse effects of the sweetener. The agency concluded that only well-controlled clinical trials focusing on specific endpoints could provide evidence for the existence of such a link. (Indeed, the United States Supreme Court has characterized anecdotal evidence as "treacherous." *Weinberger v. Hynson, Westcott and Dunning*, 412 U.S. 609,629 (1973).) Accordingly, the data and information submitted by ACSN are not reliable and thus, cannot serve as the basis for a hearing. 21 CFR 12.24(b)(2).

*B. Seizures and Adverse Reactions of Airline Pilots*

ACSN's second objection asserts that "hundreds of pilots have reported adverse reactions including grand mal seizures" and that many pilots have lost their certification to fly because of consumption of aspartame. In support of this second objection, ACSN submitted individual testimonials and case reports allegedly reflecting untoward reactions to aspartame, news articles on pilots and aspartame, and letters from aviation industry consultants.

FDA is overruling ACSN's second objection and denying its hearing request on this issue because the agency has previously considered in prior administrative proceedings on aspartame whether consumption of the sweetener causes seizures. Specifically, in responding in November 1986, to the CNI petition to revoke aspartame's approvals, FDA considered the possible link between aspartame consumption and seizure onset. The agency concluded that there was no reliable evidence from controlled clinical trials or other research that aspartame consumption is not safe (Ref. 2), a position subsequently reiterated in the agency's March 2, 1988, denial of a hearing request on amendments to the aspartame regulation (53 FR 6595 and 6597, March 2, 1988). Once an issue has been considered in a prior proceeding, a party is estopped from raising that same issue in a subsequent proceeding in the absence of new evidence.

In the present case, ACSN's objection neither identifies nor contains any reliable new data that would provide a basis for reconsideration of this factual issue by FDA. ACSN submitted only individual testimonials and case reports to support its assertions. This information is simply more of the type previously submitted in support of the alleged link between aspartame and various adverse reactions and, as noted in the discussion of objection 1, is not a reliable basis for determining a link between consumption of aspartame and such reactions. In the absence of new, reliable information, FDA need not hold a hearing on this factual issue. 21 CFR 12.24(b)(2).

*C. Lack of Warning to PKU Children and Adults*

ACSN's third objection asserted that PKU children and adults, as well as others wishing to avoid aspartame, will be unable to do so because there will be no warning label on aspartame-containing foods when served in the home and other social settings. ACSN also asserted that there are 20 million PKU gene carriers who are also at risk from consumption of aspartame. In support of this third objection, ACSN filed a sheet "Facts You Should Know About Aspartame or NutraSweet."

FDA is overruling this objection and denying ACSN's request for a hearing on this issue because the issue has previously been considered by FDA in prior proceedings on aspartame. ACSN's assertion that PKU adults and children will be unable to avoid aspartame if the sweetener is permitted in frozen, ready-to-eat cheesecakes, fruits, and fruit toppings is simply a restatement of the basic issue of aspartame's safety when eaten in moderation by average consumers. In a number of prior administrative proceedings, including the final decision of the Commissioner of Food and Drugs on aspartame's initial approval (46 FR 38285, July 24, 1981), the denial of the hearing request on aspartame's approval for use in carbonated beverages (49 FR 6672, February 22, 1984), and the November 21, 1986, denial of CNI's citizen petition to revoke all approved uses of aspartame (Ref. 2), FDA considered the safety of aspartame and concluded that there is a reasonable certainty of no harm from consumption of the additive.

ACSN has neither identified nor filed new reliable data or information to support its assertions on this point. In view of the prior consideration and in the absence of new data, no hearing need be held on this factual issue.

FDA is also denying ACSN's third objection to the extent that it asserts that PKU heterozygotes are at risk from consumption of aspartame. First, ACSN did not identify or file any data or information in support of this aspect of its third objection. Therefore, no hearing is required to be held on this issue. 21 CFR 12.24(b)(2). In addition, in the context of the Commissioner's final decision on aspartame, FDA concluded that there is no evidence that PKU heterozygotes are adversely affected by ingestion of aspartame (46 FR 38285 at 38287–38288, 38290–38291, and 38303–38305). The agency is not required to hold a hearing where, as here, the same issue was raised and considered in a prior proceeding and the objector has filed no new data or information.

*D. Risk of Aspartame Use During Pregnancy*

ACSN's fourth objection asserts that use of aspartame during pregnancy can cause mental retardation and other birth defects. ACSN asserts that Drs. Louis Elsas and William Partridge have warned against aspartame use during pregnancy. However, ACSN did not identify or file data or other information in support of this objection.

The agency is denying ACSN's fourth objection for two reasons. First, as noted, ACSN filed no data or other information to support its assertions about aspartame's relationship to birth defects. A hearing will not be granted on the basis of mere allegations or general descriptions of positions. 21 CFR 12.24(b)(2).

Secondly, in its prior decisions on the safety of aspartame, FDA considered the risks that high levels of the amino acid phenylalanine pose to the developing fetus (46 FR 38285 at 38290–38291 and 38303–38305, July 24, 1981; 53 FR 6595 at 6598–6600, March 2, 1988). At that time, FDA explained that eliminating aspartame from new products is an ineffective means of preventing birth defects because there are multiple sources of dietary phenylalanine, of which aspartame is only a relatively minor one. Thus, to prevent retardation and birth defects from elevated phenylalanine blood levels, the cause of the elevation must be diagnosed and all dietary sources of phenylalanine restricted. ACSN has filed no new data or information that dispute FDA's previous findings on this factual issue. In such circumstances, a hearing need not be granted.

**IV. Analysis of Other Objections**

In addition to ACSN, four consumers filed objections to the final aspartame rules, but did not request a hearing on any of these objections. Because there was considerable overlap, FDA has combined the objections in the agency's response to them set out below.

*A. Lack of Comprehensive Human Testing*

One objection asserted that FDA has not been provided with comprehensive human test data or studies to establish the safety of aspartame. In support of this assertion, the objection stated that: (1) Rodents do not metabolize "aspartic and phenylalanine acids" in the same manner as humans; (2) FDA overrode the objections and recommendations of the 1975 and 1977 FDA Task Forces, and the 1980 Public Board of Inquiry on aspartame; (3) FDA considered the monkey study pivotal and that this study demonstrated the toxicity of aspartame; and (4) there are an increasing number of consumer reports of the harmful effects of aspartame usage which FDA is ignoring. To support this objection, the objector submitted a chronology from 1969 to 1986 that arguably relates to aspartame, a list of scientists who have conducted studies on the reported adverse effects of aspartame, and a list of publications dealing with aspartame's safety.

The agency has considered this first objection and, as discussed below, has determined that it provides no basis for reconsideration or alteration of the final rules at issue. First, the objector did not identify any data or other information to support its assertion that additional studies of aspartame in humans are necessary to establish the safety of the additive. In fact, there have been extensive clinical studies of aspartame, including tests in children, infants, and obese, diabetic, and normal adults; doses of aspartame in these studies have ranged from very large acute doses to more moderate subchronic (13 to 28 weeks) doses. FDA considered and discussed these human test data in prior proceedings involving aspartame (46 FR 38285 at 38292–38294, July 24, 1981; 49 FR 6672 at 6680, February 22, 1984; 48 FR 31376 at 31381, July 8, 1983). Importantly, these clinical studies are only a portion of the scientific data that support the agency's determination that the additive is safe, which data are discussed in the Commissioner's final decision (46 FR 38285 at 38289–38301, July 24, 1981). Likewise, the objector filed no data or information to support its claims concerning rat metabolism. Finally, the objector provided only anecdotal case reports to support its assertion that aspartame has harmful effects, which, as discussed above, are not an adequate basis for support. Accordingly, FDA is overruling this objection.

*B. Change in ADI for Aspartame*

A second objection asserted that no safe level of aspartame has been established and that FDA originally set the safe maximum daily intake for aspartame at 20 mg/kg/day and then increased it to 50 mg/kg/day without requiring new testing. The objection further asserts that aspartame should have been examined and tested as a drug instead of a food additive. The objector relies upon the data and information identified in objection 1 above to support this objection.

FDA has considered this second objection and has determined, as set out below, that it provides no basis for reconsideration or alteration of the final rules at issue.

First, no objector provided any data or other information to demonstrate that the current acceptable daily intake (ADI) of 50 mg/kg of body weight/day is inadequate. The objector correctly asserts that the original aspartame ADI was 20 mg/kg of body weight/day. However, additional clinical testing data were provided by the petitioner to support a revision of the ADI to 50 mg/kg of body weight/day. In prior administrative proceedings concerning aspartame, FDA discussed the basis for this revision of the ADI (49 FR 6672 at 6678, February 22, 1984). Second, the objector provided no support for its assertion that aspartame should have been tested as a drug. To the contrary, aspartame meets the definition of a food additive, 21 U.S.C. 321(s), not the definition of a drug, 21 U.S.C. 321(g), in the Federal Food, Drug, and Cosmetic Act and thus, should be tested, evaluated, and regulated as such. Accordingly, because no objector has provided any basis for impeaching the current ADI or for testing and regulating aspartame as a drug, FDA is overruling this second objection.

*C. Risks Posed by DKP and Methanol*

A third objection expressed a concern about two breakdown products of aspartame: Diketopiperazine (DKP) and methanol. The objection asserted that DKP is a cancer-causing substance that occurs in large amounts if aspartame is stored for an extended period of time, especially at elevated temperatures. The objection also challenges FDA's position that the methanol that results from

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.

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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.

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(c) * * *

(3) Breakfast cereals.

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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**

of May 15, 1989 (54 FR 20924), FDA announced that a food additive petition (FAP 9A4143) had been filed by General Foods USA, 250 North St., White Plains, NY 10625, proposing that the food additive regulations be amended to include the use of aspartame in refrigerated ready-to-serve puddings and fillings.

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 by revising 21 CFR 172.804(c)(13) to read 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)(13) to read as follows:

**§ 172.804 Aspartame.**

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(c) * * *

(13) Refrigerated ready-to-serve gelatins, puddings, and fillings.

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Dated: January 24, 1992.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 92-2239 Filed 1-29-92; 8:45 am]

BILLING CODE 4160-01-M