Rules and Regulations

Federal Register
Vol. 58, No. 73
Monday, April 19, 1993

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No. 27262]

High Density Traffic Airports; Slot Allocation and Transfer Method

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Statement of policy.

SUMMARY: This policy statement is issued in response to a March 22, 1993, letter sent to the FAA by the Air Transport Association (ATA) on behalf of its members. In its letter, ATA expresses its concern about the closing of several High Density Traffic airports due to severe weather conditions on March 13–15, 1993, and the impact of the airport closings upon slot utilization requirements.

EFFECTIVE DATE: April 19, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia R. Lane, Manager, Air Traffic and Airspace Law Branch, AGC–230, Regulations Division, Office of the Chief Counsel, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3491.

Background

On August 18, 1992, the FAA published in the **Federal Register** (57 FR 37308), an amendment to the minimum slot usage requirement of § 93.227(a) of the Federal Aviation Regulations (14 CFR 93.227(a)). This amendment increased the minimum slot usage percentage from 65 percent to 80 percent, effective on January 1, 1993. A slot that is not used or operated a minimum of 80 percent of the time within the bimonthly reporting period is subject to withdrawal by the FAA.

On March 13–15, 1993, several airports, including three of the High Density Traffic airports, were forced to close because of severe weather conditions along the east coast of the United States. Due to the airport closings, many air carriers and commuters were unable to operate their slots. Many of the carriers, through ATA, have expressed concerns that they will not be able to reach the 80 percent minimum usage requirement due to their inability to operate their slots during those 3 days.

Even though the 80 percent minimum usage requirement takes various adverse factors into account, such as occasional mechanical problems and bad weather, the blizzard that forced the closure of the airports was an extraordinary weather system of great intensity and duration, and should not be considered as a normal bad weather occurrence. The FAA has decided, based on the extreme adverse weather, that operators should not be penalized if they are unable to reach the 80 percent minimum usage requirement due to the 3-day airport closure.

This notice announces FAA's policy that will allow slot holders and operators to report the slots as being used for all 3 days. In this way, no operator will be in jeopardy of losing a slot merely because the airport was closed.

Statement of Policy

When an operator submits its bimonthly use-or-lose report, it may designate any slot scheduled for operation at a High Density Traffic airport on March 13–15, 1993, as operated. The FAA's Office of Chief Counsel, Slot Administration Office will verify that the submitted slot was scheduled, and the FAA will treat as used any slot that the holder-of-record or operator-of-record was scheduled to operate over the specified 3-day period.

Issued in Washington, DC on April 13, 1993.

Joseph M. Del Balzo,

Acting Administrator.

[FR Doc. 93–9087 Filed 4–16–93; 8:45 am]
BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 400

Advertising and Labeling as to Size of Sleeping Bags

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission (the "Commission") is requesting public comments on its Trade Regulation Rule relating to the Advertising and Labeling as to Size of Sleeping Bags ("Sleeping Bag Rule"). The Commission is soliciting the comments as part of its periodic review of rules and guides.

DATES: Written comments will be accepted until May 19, 1993.

ADDRESSES: Comments should be directed to: Secretary, Federal Trade Commission, room H–159, Sixth and Pennsylvania Avenue NW., Washington, DC 20580. Comments about the Sleeping Bag Rule should be identified as "16 CFR Part 400—Comment."

FOR FURTHER INFORMATION CONTACT: John A. Crowley, Attorney, Federal Trade Commission, Washington, DC 20580, (202) 326–3280.

SUPPLEMENTARY INFORMATION: The Commission has determined, as part of its oversight responsibilities, to review rules and guides periodically. These reviews will seek information about the costs and benefits of the Commission's rules and guides and their regulatory and economic impact. The information obtained will assist the Commission in identifying rules and guides that warrant modification or recision.

At this time, the Commission solicits written public comments concerning the Commission's Trade Regulation Rule relating to the Advertising and Labeling as to Size of Sleeping Bags.

The Sleeping Bag Rule regulates the advertising, labeling and marking of the dimensions of sleeping bags. The Commission found that the practice of labeling sleeping bags by the dimensions of the unfinished sizes of material used in their construction was misleading consumers about the actual finished size of sleeping bags. To correct this misconception, the Sleeping Bag Rule provides that it is an unfair method of competition and an unfair or deceptive act or practice to use the "cut size" to describe the size of a sleeping bag in advertising, labeling or marking unless:

(1) The dimensions of the cut size are accurate measurements of the yard goods used in construction of the sleeping bags; and

(2) Such "cut size" dimensions are accompanied by the words "cut size"; and

(3) The reference to "cut size" is accompanied by a clear and conspicuous disclosure of the length and width of the finished products and by an explanation that such dimensions constitute the finished size. The rule then gives an example of proper size marking: "Finished size 33" x 68"; cut size 36" x 72"."

The rule includes examples of both proper and improper representations of size descriptions. Currently, these examples are expressed in terms of feet. Under Executive Order 12770 of July 25, 1991, and the Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act, all federal agencies are required to use the SI metric system of measurement in all procurement, grants and other business-related activities (which includes rulemakings), except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms. To comply with these provisions, should the Commission elect to retain the rule after conducting this review, the examples in the rule will be altered to include the metric equivalent in parentheses beside the English measurements. Thus, the measurements in the examples would be revised to read: "Finished size 33" x 68" (83.82 cm x 172.72 cm); cut size 36" x 72" (91.44 cm x 182.88 cm)". This is a technical amendment to an illustrative example in the rule rather than a substantive amendment to the rule. It is not intended to create any new requirement under the Rule to use metric or to use metric in any particular fashion (for example, in hundredths of centimeters). Thus, under the Administrative Procedure Act, no formal rulemaking proceeding is necessary to implement this revision.

Accordingly, the Commission solicits public comments on the following questions:

(1) Has this trade regulation rule had a significant economic impact (costs or benefits) on entities subject to its requirements?

(2) Is there a continuing need for this trade regulation rule?

(3) What burdens does compliance with this trade regulation rule place on entities subject to its requirements?

(4) What changes should be made to this trade regulation rule to minimize the economic effect on such entities?

(5) Does this trade regulation rule overlap or conflict with other federal, state, or local government laws or regulations?

(6) Have technology or economic conditions changed since this trade regulation rule was issued, and, if so, what effect do the changes have on the rule?

Authority: 15 U.S.C. 41–58.

List of Subjects in 16 CFR Part 400

Advertising, Labeling, Size, Sleeping bags.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–9092 Filed 4–16–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 90F–0115]

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

AGENCY: Food and Drug Administration, HHS.

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 additional nonalcoholic beverages including ready-to-serve fruit and nonfruit-flavored beverages and their concentrates. This action is in response to a petition filed by Kraft General Foods (formerly General Foods USA).

DATES: Effective April 19, 1993; written objections and requests for a hearing by May 19, 1993.

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: F. Owen Fields, Center for Food Safety and Applied Nutrition (HFF–333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9523.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 16, 1990 (55 FR 14133), FDA announced that a food additive petition (FAP 0A4198) had been filed by General Foods USA, 250 North St., White Plains, NY 10625 (now Kraft General Foods), proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in all nonalcoholic beverages where its use is not currently permitted. However, the petition does not include information supporting the use of aspartame in all nonalcoholic beverages. Therefore, the agency evaluated the safety of the use of aspartame only in certain nonalcoholic beverages, as described more fully below.

After review of the petition was complete, a comment was received on behalf of the Stroh Brewery Co. (the Stroh comment), requesting that FDA construe any amendments to the aspartame regulation resulting from this petition as authorizing the use of aspartame in nonalcoholic beer. The use of aspartame in nonalcoholic beer was not considered during review of FAP 0A4198 because the petition did not provide data to support such use. For this reason, the use requested in the Stroh comment is not included in this amendment to the regulation. Subsequently, Stroh Brewery Co. filed a petition (FAP 2A4324) proposing that the food additive regulations be amended to provide for the safe use of aspartame in beer containing less than 3 percent alcohol by volume (57 FR 27055, June 17, 1992). Thus, the use requested in the Stroh comment is currently under agency review.

FDA has evaluated the data in the petition and other relevant information and has determined that the use of aspartame in the following additional beverages is safe: fruit-flavored and fruit juices that are nonrefrigerated and not pasteurized or aseptically packaged (e.g., canned lemonade-type drinks); refrigerated and nonrefrigerated nonfruit-flavored beverages (e.g., canned ice teas); and nonrefrigerated pasteurized or aseptically packaged diluted fruit juice beverages drinks with a pH above 4.5 to which the additive is added prior to pasteurization. Accordingly, the agency concludes that the regulations should be amended in § 172.804(c) to permit these additional uses.

Because the existing approvals for aspartame were granted in response to a series of different petitions, the current regulations authorize nonalcoholic beverage uses in five different paragraphs. The current decision to permit use of aspartame in additional nonalcoholic beverages removes the need for specifying each individual beverage. Therefore, FDA is revising the regulations prescribing approved uses of aspartame both to add the additional uses set forth above and to simplify the regulation by grouping most permitted uses of aspartame in nonalcoholic beverages and beverage bases into § 172.804(c)(5) and (c)(6). The agency is revising § 172.804(c)(5) to

include the dry bases for tea beverages currently listed in paragraph (c)(11) and is revising paragraph (c)(6) to allow the use of aspartame as a sweetener in additional nonalcoholic beverages. The agency is removing and reserving § 172.804(c)(8), (c)(11), and (c)(12) and incorporating all of those permitted uses into either paragraph (c)(5) or (c)(6). The previously allowed uses of aspartame in fruit flavored drinks and ades, imitation fruit flavored drinks and ades, tea beverages, and carbonated beverages are now listed as "flavored beverages." Fruit juice based drinks and ready-to-serve nonrefrigerated, pasteurized, aseptically packaged diluted fruit juice beverages are now included in the listing as "fruit juice based beverages."

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 May 19, 1993, 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 and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 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 paragraphs (c)(5)(ii) and (c)(6) and by removing and reserving paragraphs (c)(8), (c)(11), and (c)(12) to read as follows:

§ 172.804 Aspartame.

* * * * *

(c) * * *

(5) * * *

(ii) Instant coffee and tea beverages.

* * * * *

(6) Ready-to-serve nonalcoholic flavored beverages, tea beverages, fruit juice based beverages, and their concentrates or syrups.

* * * * *

Dated: March 25, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–8777 Filed 4–16–93; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 172

[Docket No. 92F–0214]

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

AGENCY: Food and Drug Administration, HHS.

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 flavor enhancer in malt beverages containing less than 3 percent alcohol by volume. This action is in response to a petition filed by the Stroh Brewery Co.

DATES: Effective April 19, 1993; written objections and requests for a hearing by May 19, 1993.

ADDRESSES: Submit 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: F. Owen Fields, Center for Food Safety and Applied Nutrition (HFS–207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9523.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 17, 1992 (57 FR 27055), FDA announced that a food additive petition (FAP 2A4324) had been filed by 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 in beer containing less than 3 percent alcohol by volume. The petitioner demonstrated that the addition of aspartame to such beverages, even at levels below the threshold of sweetness, results in a product with improved flavor qualities. Thus, the technical effect of aspartame described in this petition is that of a flavor enhancer rather than a sweetener.

In FAP 2A4324, Stroh used the terms "beer containing less than 3% alcohol by volume" and "malt beverages containing less than 3% alcohol by volume" interchangeably. Because FDA believed that these terms were interchangeable, the agency used the more common term "beer" in its notice of filing for FAP 2A4324. However, subsequent to publication of the filing notice, FDA determined that Bureau of Alcohol, Tobacco, and Firearms (BATF) regulations (27 CFR 7.24(d)) state that "Products containing less than one-half of 1 percent (.5%) of alcohol by volume shall bear the class designation 'malt beverage' or 'cereal beverage,' or 'near beer'" and that "No product containing less than one-half of 1 percent of alcohol by volume shall bear the class designations 'beer', 'lager beer', 'lager', 'ale', 'porter', or 'stout', or any other class or type designation commonly applied to malt beverages containing one-half of 1 percent or more of alcohol by volume." Because the petitioner

intended, and FDA evaluated, use of aspartame as a flavor enhancer in all malt-based beverages containing less than 3% alcohol by volume (including those containing less than 0.5% alcohol), the agency, in order to be consistent with BATF regulations, will refer to these products in the regulation as "malt beverages" rather than as "beer."

Having evaluated data in the petition and other relevant material, the agency concludes that the proposed use of the food additive is safe, and that the regulations should be amended in § 172.804(d) 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 May 19, 1993, 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 and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 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 (d) to read as follows:

§ 172.804 Aspartame.

* * * * *

(d) The additive may be used as a flavor enhancer in chewing gum, hard candy, and malt beverages containing less than 3 percent alcohol by volume.

* * * * *

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–8778 Filed 4–16–93; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 172

[Docket No. 87F–0344]

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

AGENCY: Food and Drug Administration, HHS.

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 baked goods and baking mixes where standards of identity do not preclude its use. Generally recognized as safe (GRAS) ingredients or approved food additives shall be used to ensure aspartame functionality in the final baked product. This action is in response to a petition filed by the NutraSweet Co.

DATES: Effective April 19, 1993; written objections and requests for a hearing by May 19, 1993. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 172.804(c)(23), effective April 19, 1993.

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: F. Owen Fields, Center for Food Safety and Applied Nutrition (HFS–207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9523.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 20, 1987 (52 FR 44636), FDA announced that a food additive petition (FAP 7A4044) had been filed by the NutraSweet Co., 1751 Lake Cook Rd., Deerfield, IL 60015, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in baked goods and baking mixes where standards of identity do not preclude its use.

Aspartame breaks down to diketopiperazine (DKP) when exposed to prolonged heat, resulting in a loss of sweetness. For this reason, aspartame has not previously been considered for use in baking. When aspartame is used in a sugar substitute for table use, its label is required to include instructions not to use it in cooking or baking (21 CFR 172.804(e)(3)). The NutraSweet Co. has now developed technology for combining safe and suitable ingredients (substances that are GRAS or food additives used in compliance with a regulation) with aspartame to delay its breakdown at temperatures normally used in baking (U.S. Patent No. 4,704,288 Heat Stabilized Sweetener Composition Containing Aspartame). Aspartame protected in this way is effective as a sweetener in baked goods and baking mixes.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe and the regulations should be amended by adding § 172.804(c)(23) as set forth below. Because stabilizing ingredients are needed to inhibit decomposition of aspartame under the conditions of use

involved in baking, the regulation specifies that GRAS ingredients or approved food additives are to be used to ensure aspartame functionality in the final baked product. In addition, FDA is setting a maximum use level of 0.5 percent (5,000 parts per million) in refrigerated or frozen ready-to-bake products and finished formulations prepared for baking from commercial dry mixes or from individual ingredients. Assuming the expected level of breakdown to DKP of aspartame with suitable thermal protection, this maximum prebaking level of aspartame in baked goods and baking mixes will ensure that the final level of aspartame will provide adequate sweetening. Excessive decomposition at this maximum use level would result in a lack of aspartame functionality. Because ensuring aspartame functionality in the final product is part of current good manufacturing practice (CGMP), FDA is not requiring specific ingredients or conditions for stabilization. This limitation on aspartame levels does not represent a conclusion by FDA that greater levels are unsafe, but ensures that manufacturers follow the CGMP requirements found in § 172.5(a)(1) and avoid use of aspartame formulations with inadequate thermal stabilization. FDA is incorporating by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, an analytical method to determine the level of aspartame in ready-to-bake products and finished formulations prior to baking.

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 May 19, 1993, 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, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 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 adding new paragraph (c)(23) to read as follows:

§ 172.804 Aspartame.

* * * * *

(c) * * *

(23) Baked goods and baking mixes in an amount not to exceed 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. Generally recognized as safe (GRAS) ingredients or food additives approved for use in baked goods shall be used in combination with aspartame to ensure its functionality as a sweetener in the final baked product. The level of aspartame used in these products is determined by an analytical method entitled "Analytical Method for the Determination of Aspartame and Diketopiperazine in Baked Goods and Baking Mixes," October 8, 1992, which was developed by the NutraSweet Co., and is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, or are available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–8779 Filed 4–16–93; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 172

[Docket No. 90F–0017]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Modified Food Starch Treated with Beta-Amylase Enzyme

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of food starch modified by esterification with 1-octenyl succinic anhydride and treated with *beta*-amylase enzyme to be used as a stabilizer or emulsifier in nonalcoholic beverages and beverage bases. This action is in response to a petition filed by the National Starch and Chemical Corp. of North America.

DATES: Effective April 19, 1993; written objections and requests for a hearing by May 19, 1993.

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: Vincent Zenger, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9523.

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

January 31, 1990 (55 FR 3269), FDA announced that a food additive petition (FAP 9A4136) had been filed by National Starch and Chemical Corp. of North America, Finderne Ave., P.O. Box 6500, Bridgewater, NJ 08807, proposing that the food additive regulations be amended to provide for the safe use of *beta*-amylase to treat modified food starch. In fact, the food additive under review is modified food starch, not *beta*-amylase. Thus, the petition requested, and the agency evaluated, the safety of starch modified by esterification with 1-octenyl succinic anhydride and treated with *beta*-amylase.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that food starch that is modified by esterification with 1-octenyl succinic anhydride and treated with *beta*-amylase and is to be used as a stabilizer or emulsifier in nonalcoholic beverages and beverage bases, as defined in § 170.3(n)(3) (21 CFR 170.3(n)(3)) is safe. The agency notes that § 170.3(n)(3) contains a list of specific beverages and beverage bases that the beverages covered are restricted to those listed, and that the list of beverages does not include infant formulas. The reading of § 170.3(n)(3) is consistent with the 1972 report of the National Academy of Sciences/National Research Council, "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe," which is the basis for the categories set out in § 170.3(n). Accordingly, the agency concludes that the regulations should be amended in § 172.892(d) (21 CFR 172.892(d)) 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 May 19, 1993, 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 and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 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 172.892 is amended by alphabetically adding a new entry in the table in paragraph (d) to read as follows:

§ 172.892 Food starch-modified.

* * * * *

(d) * * *

	Limitations
* * * * * * *	
1-Octenyl succinic anhydride, not to exceed 3 percent, followed by treatment with a *beta*-amylase enzyme that is either an approved food additive or is generally recognized as safe..	Limited to use as a stabilizer or emulsifier in beverages and beverage bases as defined in § 170.3(n)(3) of this chapter.
* * * * * * *	

* * * * *

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–9061 Filed 4–16–93; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 176

[Docket No. 85F–0234]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2-amino-2-methyl-1-propanol as a dispersing agent in pigment suspensions to be applied as coatings to paper and paperboard products intended for contact with aqueous foods, including acidic and alcoholic foods. This action responds to a food additive petition filed by Angus Chemical Co.

DATES: Effective April 19, 1993; written objections and requests for a hearing by May 19, 1993.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug