(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

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**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

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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

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**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

Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.
FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 9, 1985 (50 FR 28033), FDA announced that a food additive petition (FAP 5B3851) had been filed by Angus Chemical Co., 2211 Sanders Rd., Northbrook, IL 60062, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended 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 food-contact use with aqueous foods.

This amendment to § 176.170 reflects that the additive is now cleared for use with all food types. The previously regulated uses of the additive with food types V, VIII, and IX, identified in Table 1 of § 176.170(c), combined with the new uses, give clearance for use of the additive with all food types.

In its evaluation of the additive, FDA reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although 2-amino-2-methyl-1-propanol has not been found to cause cancer, it may contain residual amounts of 2-nitropropane which has been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as 2-nitropropane, are commonly found as contaminants in chemical products, including food additives. Therefore, the agency has evaluated the potential ingestion of this carcinogenic substance from its use in coatings for paper and paperboard products in contact with food.

## I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance" (H. Rept. 2284, 85th Cong., 2d sess. 4 (1958)). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer, or Delaney, clause of the act (section 409(c)(3)(A)) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that has not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

## II. Safety of the Petitioned Use

FDA estimates that the petitioned use of 2-amino-2-methyl-1-propanol will result in extremely low levels of exposure to this additive. The agency has estimated a probable daily intake of 2-amino-2-methyl-1-propanol based on considerations such as the migration of the additive under the most severe intended use conditions and the probable concentration of the additive in food from food-contact articles that contain this substance. The concentration of the additive in the daily diet resulting from the proposed use in coatings for contact with aqueous foods, including acidic and alcoholic foods, is expected to be no greater than 0.11 part per million.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing in this case. However, the agency has reviewed available data from a 1-year feeding study in dogs and other data. Based on this study and other data, and the low level of exposure to 2-amino-2-methyl-1-propanol, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

Because 2-amino-2-methyl-1-propanol itself has not been shown to cause cancer, the anticancer clause of the act does not apply to it. However, FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemical, 2-nitropropane, that may be present as an impurity in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see e.g., 49 FR 13018 at 13019, April 2, 1984). This risk evaluation of the carcinogenic impurity, 2-nitropropane, has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

### *A. 2-Nitropropane*

Based on the fraction of the daily diet that may be in contact with surfaces containing 2-amino-2-methyl-1-propanol and on the level of 2-nitropropane that may be present in the additive, FDA estimated the hypothetical worst-case exposure to 2-nitropropane from the use of 2-amino-2-methyl-1-propanol in pigmented coatings contacting: (1) Aqueous foods, including acidic and alcoholic foods, to

be 0.6 nanogram per person per day (ng/p/d), and (2) when in contact with all types of foods, to be 1 ng/p/d (Refs. 3 and 4).

The agency used data from three inhalation studies on 2-nitropropane with rats to estimate the upper-bound limit of lifetime human risk from exposure to this chemical stemming from the proposed use of 2-amino-2-methyl-1-propanol (Refs. 5, 6, and 7). The results of these bioassays demonstrated that 2-nitropropane was carcinogenic in rats under the conditions of the study. The test material caused significantly increased incidences of hepatocellular tumors in male and female rats by the inhalation route.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed these bioassays and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 2-nitropropane (Ref. 8). The committee further concluded that an estimate of the upper-bound level of lifetime human risk from potential exposure to 2-nitropropane stemming from the proposed use of 2-amino-2-methyl-1-propanol could be calculated from the bioassays.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the rat experiments to the very low doses that might be encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine with reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additive.

Based on a worst-case exposure of no more than 1 ng/p/d, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to 2-nitropropane from the use of 2-amino-2-methyl-1-propanol in pigmented coatings contacting all types of food is $6 \times 10^{-10}$ or 6 in 10 billion (Ref. 9). Because of numerous conservatisms in the exposure estimate, actual lifetime averaged individual daily exposure to 2-nitropropane is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound limit of risk would be less than $6 \times 10^{-10}$. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to 2-nitropropane that might result from the proposed use of 2-amino-2-methyl-1-propanol in contact with food.

*B. Need for Specifications*

The agency has also considered whether a specification is necessary to control the amount of 2-nitropropane impurity in the food additive. The agency finds that a specification is not necessary for the following reasons: (1) Because of the low level at which 2-nitropropane may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to this impurity, even under worst case assumptions, is very low, 6 in 10 billion.

*C. Conclusion on Safety*

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed uses for the additive in paper and paperboard products in contact with aqueous foods, including acidic and alcoholic foods, is safe, and § 176.170 should be amended 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.

## III. Environmental Impact

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.

## IV. Objections

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.

## V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G. M., "Carcinogen Testing Programs," in "Food Safety: Where are We?," Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.

2. Kokoski, C. J., "Regulatory Food Additive Toxicology," in "Chemical Safety Regulation and Compliance," edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.

3. Memorandum dated August 30, 1985, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "FAP 5B3851—2-Nitropropane (2–NP)."

4. Memorandum dated September 25, 1985, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "FAPs 0B3486 & 5B3851. 2-Nitropropane (2NP) and Formaldehyde."

5. Griffin, T. B., K. F. Benitz, R. Coulston, and I. Rosenblum, "Chronic Inhalation Toxicity of 2-Nitropropane in Rats" (Abstract No. 3), *The Pharmacologist*, 20:145, 1978.

6. Griffin, T. B., F. Coulston, and A. A. Stein, "Chronic Inhalation Exposure of Rats to Vapors of 2-Nitropropane at 25 ppm," *Ecotoxicology Environmental Safety*, 4:267-281, 1980.

7. Griffin, T. B., A. A. Stein, and F. Coulston, "Histologic Study of Tissue and Organs from Rats Exposed to Vapors of 2-Nitropropane at 25 ppm," *Ecotoxicology Environmental Safety*, 5:194-201, 1981.

8. Memorandum of conference, from the Cancer Assessment Committee, "2-Nitropropane," dated August 12, 1983.

9. Memorandum from the Quantitative Risk Assessment Committee, "Risk Assessments for the Presence of the Carcinogen, 2-Nitropropane, in Food," dated April 7, 1986.

**List of Subjects in 21 CFR Part 176**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

## PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

**Authority:** Secs. 201, 402, 406, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 376).

2. Section 176.170 is amended in the table in paragraph (a)(5) by revising the entry for "2-Amino-2-methyl-1-propanol (CAS Reg. No. 124–68–5)" under the heading "Limitations" to read as follows:

**§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.**

* * * * *

(a) * * *

(5) * * *

| List of Substances | Limitations |
|---|---|
| * * * * * * * | |
| 2-Amino-2-methyl-1-propanol (CAS Reg. No. 124–68–5) | For use as a dispersant for pigment suspension at a level not to exceed 0.25 percent by weight of pigment. The suspension is used as a component of coatings for paper and paperboard under conditions of use described in paragraph (c) of this section, Table 2, conditions of use E through G. |
| * * * * * * * | |

* * * * *

Dated: April 8, 1993.

**Michael R. Taylor,**

*Deputy Commissioner for Policy.*

[FR Doc. 93–9063 Filed 4–16–93; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

### 30 CFR Part 75

RIN 1219–AA11

### Safety Standards for Underground Coal Mine Ventilation; Correction

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Correction.

**SUMMARY:** This document corrects the preamble to the final rule for safety standards for underground coal mine ventilation that appeared in the Federal Register on May 15, 1992 (57 FR 20868).

**EFFECTIVE DATE:** April 19, 1993.

**FOR FURTHER INFORMATION CONTACT:** Patricia W. Silvey, Director, Office of Standards, Regulations and Variances, MSHA, phone (703) 235–1910.

**SUPPLEMENTARY INFORMATION:**

**Background**

On May 15, 1992, MSHA published a final rule to revise its safety standards for underground coal mine ventilation. This document deletes language that erroneously appeared in the preamble discussion of the definition of "air course".

On page 20870, in the second column under "Section 75.301 Definitions", first paragraph, the second sentence reads, "The Agency does not consider air courses that are common only at each end to be the same air course if the separation between the common openings is more than 600 feet."

After reviewing the preamble and the definition of air course in the rule, MSHA has found that the sentence is inconsistent with both other language in the preamble and the final rule itself. In particular, this sentence conflicts with the immediately preceding paragraph in the preamble discussion of the definition of air course. Because it was inadvertently included in the preamble and MSHA did not intend that an air course be interpreted consistent with that sentence this notice deletes the sentence.

**Correction of Publication**

In the preamble to the final rule for safety standards for underground coal mine ventilation that appeared in the Federal Register on May 15, 1992 (57 FR 20868), the following correction is made:

1. On page 20870, in the second column under "Section 75.301 Definitions", first paragraph, the second sentence, which reads, "The Agency does not consider air courses that are common only at each end to be the same air course if the separation between the common openings is more than 600 feet" is deleted.

Dated: April 12, 1993.

**Edward C. Hugler,**

*Acting Assistant Secretary for Mine Safety and Health.*

[FR Doc. 93–8997 Filed 4–16–93; 8:45 am]

BILLING CODE 4510–43–M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

### 33 CFR Part 110

[CGD1 91–063]

### Special Anchorage Area: Deep Bay, Lake Champlain, NY

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is adopting regulations to establish a special anchorage area in Lake Champlain. This anchorage is located in the waters contiguous to Point Au Roche State Park, New York in an area known as Deep Bay. The New York State Office of Parks, Recreation and Historic Preservation requests this area be designated as a special anchorage for usage by recreational craft. This final rule will provide a safe anchorage well away from fairways where vessels not more than 65 feet in length can remain unlighted at night and during periods of reduced visibility. There are no such anchorages available in the immediate area.

**EFFECTIVE DATE:** May 19, 1993.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant (junior grade) J.J. Gleason, Waterways Management Officer, Coast Guard COTP New York (212) 668–7902.

**SUPPLEMENTARY INFORMATION:**

**Drafting Information**

The drafters of this notice are LTJG J.J. Gleason, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

**Regulatory History**

On April 14, 1992, the Coast Guard published a notice of proposed rulemaking entitled "Special Anchorage Area; Deep Bay, Lake Champlain, NY" in the **Federal Register** (57 FR 12891). The Coast Guard did not receive any letters commenting on the proposal. A public hearing was not requested and one was not held.

**Background and Purpose**

On September 12, 1991 the New York State Office of Parks, Recreation and Historic Preservation (hereafter, the State) requested this area be designated a special anchorage to facilitate the mooring of transient recreational craft. The State has documented the usage of this area over the past ten years, 1980 through 1990, and feels this designation is necessary to sanction and better manage this usage. This designation would substantially enhance the utilization of this area by providing an orderly mooring scheme. The State will administer this mooring area by issuing temporary permits for its use. The existing facilities, which include a floating dock, sewage pumpout station and a boat launch would be available to all permit holders. This area will be available to the general public and will be able to accommodate up to 63 vessels, no greater than 40 feet in length. The requestor will install State maintained aids to navigation which will mark a clear channel for ingress and egress of vessels from the mooring field.

**Regulatory Evaluation**

This regulation is not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a Regulatory Evaluation is unnecessary. The area has always been a designated anchorage ground, this regulation merely makes its utilization more available to the general population, in particular, recreational vessel operators. Establishment of this proposed special anchorage will not require dredging or result in increased cost to any segment of the public.

**Small Entities**

For reasons already specified in the Regulatory Evaluation section of this rule, the Coast Guard has determined that this rule will have a minimal adverse impact on small entities. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this final rule will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

**Federalism**

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this regulation does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**Environment**

The Coast Guard considered the environmental impact of this regulation and concluded that under section 2.B.2.c. of Commandant Instruction M16475.1B, this rule is categorically excluded from further documentation. This rule will not have any impact on the human environment or environmental conditions, in general, and is solely an administrative action which will sanction the historical use of this area. A categorical exclusion determination is available in the docket.

**List of Subjects in 33 CFR Part 110**

Anchorage grounds.

**Final Regulation**

For reasons set out in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

## PART 110—[AMENDED]

1. The authority citation for 33 CFR part 110 continues to read as follows:

**Authority:** 33 U.S.C. 471, 2030, 2035 and 2071; 49 CFR 1.46 and 33 CFR 1.05-1(g). Section 110.1a and each section listed in 110.1a are also issued under 33 U.S.C. 1223 and 1231.

2. In § 110.8, paragraph (i) is added to read as follows:

**§ 110.8 Lake Champlain, N.Y. and VT.**

* * * * *

(i) *Point Au Roche, New York.* The waters of Deep Bay north of a line drawn shore to shore along the 44°46'14"N line of Latitude.

**Note:** Anyone wishing to occupy a mooring in this area shall obtain a permit from the New York State Office of Parks, Recreation & Preservation.

Dated: April 5, 1993.

**J.D. Sipes,**

*Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.*

[FR Doc. 93–8988 Filed 4–16–93; 8:45 am]

BILLING CODE 4910–14–M

**33 CFR Part 110**

**[CGD1 91–167]**

## Special Anchorage Area: Lower Hudson River, NY

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is adopting regulations to establish a special anchorage area in the Lower Hudson River in the waters contiguous to the Manhattan shoreline. This anchorage is located north of the George Washington Bridge and changes the designation of Federal Anchorage 18–B from a general anchorage ground to a special anchorage area. The co-applicants, New York City Department of Parks & Recreation and Dyckman Marine Venture, LTD., requested this area be designated as a special anchorage area to increase access and recreation options for the public. This regulation will provide an anchorage where vessels 65 feet or less in length can remain unlighted at night and during periods of reduced visibility. There are no such anchorages available in the immediate area.

**EFFECTIVE DATE:** May 19, 1993.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant (junior grade) L. D. Johnson, Waterways Management Officer, Coast Guard COTP New York (212) 668–7902.

**SUPPLEMENTARY INFORMATION:**

**Drafting Information**

The drafters of this notice are LTJG L. D. Johnson, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

**Regulatory History**

On May 8, 1992, the Coast Guard published a notice of proposed rulemaking entitled "Special Anchorage Area; Lower Hudson River, NY" in the **Federal Register** 57 FR 19831. The Coast Guard received one (01) letter commenting on the proposal. A public hearing was not requested and one was not held.

**Background and Purpose**

The co-applicants, New York City Department of Parks & Recreation and Dyckman Marine Venture Ltd., requested this area be designated a special anchorage area to enhance access and use of this waterway, and increase the recreational options for the public. The area is presently designated a federal anchorage, FA 18–B, and is described in paragraph 110.155(c)(4), of this title. The anchorage ground, as presently designated, was established sometime prior to December 12, 1967 by

the Department of the Army. December 12, 1967 is the same date the Coast Guard assumed administrative and regulatory control of federally established anchorages. The Coast Guard does not have any record of this anchorage ground being used for its intended purpose as a commercial deep draft anchorage or as a naval vessel auxiliary anchorage. The area is used by recreational vessels under the jurisdiction of the New York City Department of Parks and Recreation. However, the city would prefer to have this area federally designated to increase the amount of mooring space available to the recreational boating population.

This designation will change this anchorage from a general anchorage ground to a special anchorage area where vessels 65 feet or less could remain unlighted at night and during periods of limited visibility without hazarding maritime traffic in the area. This area is located adjacent to the existing facilities at the Dyckman Street Marina. There are currently no such anchorages available in the immediate area. The co-applicants will administer this mooring area by issuing permits for its use and provide oversight to ensure the area is operated within applicable Coast Guard guidelines. Upon approval, the co-applicants will make available an area for docking and storage, and will also provide free sewage pumpout services for all vessels holding valid mooring permits. This special anchorage area will be available to the general public. The requestor will establish private lighted aids to navigation, approved by the Coast Guard, to ensure the area is adequately marked.

**Discussion of Comments and Changes**

The only comment received was a written response from the Towboat and Harbor Carriers Conference, a conference of the American Waterways Operators, Atlantic Region. The responder is against the establishment of this special anchorage for the following reasons; objection to changing the use of the area from a commercial to a recreational anchorage due to loss of anchorage space, objection to the preamble in the proposed rulemaking which stated that the Coast Guard had no records of commercial utilization of the anchorage, and objection to the mooring of recreational vessels along a commercial waterway due to potential wake problems and general safety concerns.

In response to those allegations the Coast Guard offers the following:

1. The area to be designated as a special anchorage is Federal Anchorage 18–B (FA18–B) which is surrounded to the north, south and west by other much larger anchorages. Federal Anchorages 16, 17, 18A and 19 are all within less than 1 mile of FA 18–B and comprise over 97 percent more anchorage area than is being lost by this designation. Federal Anchorages 16, 17, 18A and 19 are equivalent anchorages to FA 18–B and therefore the redesignation of this anchorage does not significantly reduce the amount or type of anchorage area used by non-recreational vessels. The Coast Guard received no comments from vessel owners regarding the redesignation of this anchorage.

2. The wake problem and other safety concerns are recognized. However, several other special anchorages already exist along this waterway. Although there have been some problems noted in the past regarding the interaction of commercial and recreational vessels the Coast Guard feels this should not be considered an unreasonable hazard that outweighs the benefit of additional safe moorings. For added safety, the dimensions of FA 18B were modified in the proposed regulation to facilitate its use by narrowing its western limits by 50 percent, thereby moving the anchorage further from the active channel. A private aid to navigation system will also be established in the area to better mark its bounds. No such system presently exists.

No changes to the proposal have been made to this rule as a result of the comments received.

**Regulatory Evaluation**

This regulation is not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a Regulatory Evaluation is unnecessary. The area has always been a designated anchorage ground, this regulation merely makes its utilization more available to the general population, in particular, recreational vessel operators. Establishment of this special anchorage area will not require dredging or result in increased cost to any segment of the public.

**Small Entities**

For reasons already specified in the Regulatory Evaluation section of this rule, the Coast Guard has determined that this rule will have a minimal adverse impact on small entities. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this final rule will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

**Federalism**

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this regulation does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**Environment**

The Coast Guard considered the environmental impact of this regulation and concluded that under section 2.B.2.c. of Commandant Instruction M16475.1B, this rule is categorically excluded from further documentation. This rule will not result in any significant cumulative impact on the human environment or environmental conditions, in that the proposed regulation will merely redesignate an existing anchorage. A categorical exclusion determination is available in the docket.

**List of Subjects in 33 CFR Part 110**

Anchorage grounds.

**Regulation**

For reasons set out in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

## PART 110—[AMENDED]

1. The authority citation for part 110 continues to read as follows:

**Authority:** 33 U.S.C. 471, 2030, 2035 and 2071; 49 CFR 1.46 and 33 CFR 1.05–1(g). Section 110.1a and each section listed in 110.1a are also issued under 33 U.S.C. 1223 and 1231.

2. In § 110.60, paragraph (o–3) is added after the note to read as follows:

**§ 110.60 Port of New York and vicinity.**

* * * * *

(o–3) *Hudson River, North Manhattan.* That area enclosed by coordinates starting at 40°51′08.0″ N., 073°56′36.1″ W., to 40°51′09.5″ N., 073°56′40.9″ W., to 40°52′08.1″ N., 073°55′57.0″ W., thence along the shoreline to the point of the beginning.

* * * * *

3. Section 110.155(c)(4) is removed and reserved.

Dated: April 5, 1993.

**J.D. Sipes,**

*Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.*

[FR Doc. 93-8989 Filed 4-16-93; 8:45 am]

BILLING CODE 4910-14-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MM Docket No. 92-311; RM-8132]**

### Radio Broadcasting Services; Iron River, WI

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allots Channel 297C2 to Iron River, Wisconsin, as that community's first local transmission service in response to a petition filed by James V. Lien, Norma G. Lien and Lenard G. Harvey. See 58 FR 4974, January 19, 1993. The coordinates for Channel 297C2 are 46-35-19 and 91-14-44. There is a site restriction 12.3 kilometers (7.7 miles) east of the community. Canadian concurrence has been obtained for this allotment. With this action, this proceeding is terminated.

**DATES:** Effective May 28, 1993. The window period for filing applications for Channel 297C2 at Iron River will open on June 1, 1993, and close on July 1, 1993.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, MM Docket No. 92-311, adopted March 22, 1993, and released April 13, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street NW., suite 140, Washington, DC 20037, (202) 857-3800.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Wisconsin, is amended by adding Iron River, Channel 297C2.

Federal Communications Commission.

**Michael C. Ruger,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 93-9010 Filed 4-16-93; 8:45 am]

BILLING CODE 6712-01-M

### 47 CFR Part 73

**[MM Docket No. 92-278; RM-8115]**

### Radio Broadcasting Services; Harlem, GA

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document substitutes Channel 236C3 for Channel 236A at Harlem, Georgia, at the request of GMR Broadcasting, Inc. See 57 FR 57410, December 4, 1992. Channel 236C3 can be allotted to Harlem, Georgia, in compliance with the Commission's minimum distance separation requirements with a site restriction of 13.3 kilometers (8.3 miles) northwest, in order to avoid a short-spacing to a construction permit for Station WMKO(FM), Channel 235C3, Millen, Georgia. The coordinates for Channel 236C3 at Harlem are North Latitude 33-29-22 and West Longitude 82-25-28. With this action, this proceeding is terminated.

**EFFECTIVE DATE:** May 28, 1993.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Walls, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 92-278, adopted March 17, 1993, and released April 13, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857-3800, 1919 M Street NW., room 246, or 2100 M Street NW., Suite 140, Washington, DC 20037.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by removing Channel 236A and adding Channel 236C3 at Harlem.

Federal Communications Commission.

**Michael C. Ruger,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 93-9013 Filed 4-16-93; 8:45 am]

BILLING CODE 6712-01-M

### 47 CFR Part 73

**[MM Docket No. 92-229; RM-8083]**

### Radio Broadcasting Services; Brookings, OR

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of KURY Radio, Inc., substitutes Channel 237C2 for Channel 237C3 at Brookings, Oregon, and modifies Station KURY's license to specify operation on the higher class channel. *See* 57 FR 47027, October 14, 1993. Channel 237C2 can be allotted to Brookings in compliance with the Commission's minimum distance separation requirements at Station KURY's licensed transmitter site, at coordinates North Latitude 42-07-23 and West Longitude 124-17-56. With this action, this proceeding is terminated.

**EFFECTIVE DATE:** May 28, 1993.

**FOR FURTHER INFORMATION CONTACT:** Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket No. 92-229, adopted March 24, 1993, and released April 13, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**PART 73—[AMENDED]**

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303.