1396, a proposed consent agreement with analysis In the Matter of PPG Industries, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement and made its jurisdictional findings in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Acquiring Corporate Stock Or Assets: § 13.5 Acquiring corporate stock or assets; § 13.5–20 Federal Trade Commission. Subpart—Corrective Actions And/Or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–50 Maintain means of communication.

List of Subjects in 16 CFR Part 13

Aircraft transparencies, Windows, Windshields, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

Donald S. Clark,

Secretary.

[FR Doc. 89–10776 Filed 5–4–89; 8:45 am]

BILLING CODE 6750–01–M

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16 CFR Part 13

[Docket C–3247]

Cleveland Automobile Dealers' Association; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of Federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, the Cleveland Automobile Dealers' Association (CADA) from limiting its members' hours, from maintaining any policy concerning hours of operation, and from encouraging members to influence each other as to their hours. The consent order requires respondent to advertise in the newspaper that dealers' hours are no longer restricted and also change its Articles of Incorporation or other policy statements to reflect the consent order.

DATE: Complaint and Order issued March 2, 1989.[1]

FOR FURTHER INFORMATION CONTACT: Mark Kindt or Steven Balster, Cleveland Regional Office, Federal Trade Commission, Suite 520–A, 668 Euclid Avenue, Cleveland, OH 44114. (216) 522–4210.

SUPPLEMENTARY INFORMATION: On Wednesday, December 7, 1988, there was published in the **Federal Register**, 53 FR 49329, a proposed consent agreement with analysis In the Matter of Cleveland Automobile Dealers' Association, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Coercing And Intimidating: § 13.345 Competitors; § 13.367 Members. Subpart—Combining Or Conspiring: § 13.384 Combining or conspiring; § 13.395 To control marketing practices and conditions; § 13.410 To eliminate competition in conspirators' goods; § 13.470 To restrain and monopolize trade; § 13.475 To restrict competition in buying. Subpart—Corrective Actions And/Or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–20 Disclosures; § 13.533–50 Maintain means of communication; § 13.533–60 Release of general, specific, or contractual constrictions, requirements, or restraints.

List of Subjects in 16 CFR Part 13

Automobile dealers, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 89–10775 Filed 5–4–89; 8:45 am]

BILLING CODE 6750–01–M

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16 CFR Part 453

Funeral Industry Practices Trade Regulation Rule

AGENCY: Federal Trade Commission.

[1] Copies of the Complaint, and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

ACTION: Final non-substantive amendment.

SUMMARY: This document announces the Commission's decision to issue a non-substantive amendment to § 453.10 of the Funeral Industry Practices Trade Regulation Rule (16 CFR Part 453). That section required that the Commission initiate a rulemaking proceeding to review whether the Funeral Rule should remain in effect unchanged or should be amended or repealed, and presently requires that the Commission make its final decision on the recommendations of that review proceeding eighteen months after its initiation. Under that current mandate, the Commission must act by November 30, 1989. The amendment rescinds the eighteen-month time limit for final Commission action. This removal of the mandated time limit for final Commission action is necessary to give the Commission adequate time to comply with the procedural rulemaking requirements of section 18 of the FTC Act (15 U.S.C. 57a).

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT: Matthew Daynard, Ra'ouf M. Abdullah, or Richard Kelly, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC, 20580, 202–326–3291, 202–326–3024, or 202–326–3304.

SUPPLEMENTARY INFORMATION: The Commission promulgated the Funeral Industry Practices Rule on September 24, 1982 (47 FR 42260), and the Rule became fully effective on April 30, 1984 (48 FR 45537 (1983), 49 FR 564 (1984)). The Commission's decision to promulgate the Rule was subsequently affirmed by the 4th U.S. Circuit Court in *Harry & Bryant Co.* v. *FTC*, 726 F.2d 993, *cert. denied*, 469 U.S. 820 (1984). Essentially, the Funeral Rule requires funeral providers to: (1) Disclose prices, available options and other information to consumers in person and over the telephone; (2) make truthful representations regarding legal and other requirements; (3) permit consumers to select and purchase only those goods and services they desire; (4) obtain express permission before embalming the deceased for a fee; (5) refrain from misrepresenting the protective and preservative value of funeral goods and services; and (6) disclose whether they charge a fee for arranging cash advance purchases.

Section 453.10 of the Rule requires that the Commission initiate a rulemaking amendment proceeding four years after the effective date of the Rule, and further requires that the Commission reach a final decision on

that amendment proceeding eighteen months after its initiation. That provision states:

> No later than four years after the effective date of this rule, the Commission shall initiate a rulemaking amendment proceeding pursuant to section 18(d)(2)(B) [of the FTC Act] to determine whether the rule should be amended or terminated. The Commission's final decision on the recommendations of this proceeding shall be made no later than eighteen months after the initiation of the proceeding.

On May 9, 1988, the Commission announced its decision to initiate the rulemaking amendment proceeding mandated by § 453.10 of the Rule, and on May 31, 1988 the Commission published in the **Federal Register** its notice of proposed rulemaking to review the Funeral Rule (53 FR 19864 (1988)). The current language of § 453.10 of the Rule requires that the Commission make a "final decision" on the recommendations of this amendment proceeding by November 30, 1989—eighteen months after its initiation. In order to reach its "final decision," the Commission must either vote to leave the Rule in place unchanged and terminate the proceeding, or vote to repeal or amend the Rule and publish its statement of basis and purpose explaining its decision to repeal or amend.

The Commission has determined that eighteen months is insufficient time to comply with the procedural rulemaking requirements of section 18 of the FTC Act (15 U.S.C. 57a) for this rulemaking proceeding, which, according to staff, has to date generated a high level of public participation and a voluminous record. While four sets of public hearings and a rebuttal period have been completed, the proceeding has several required rulemaking stages yet to come before the Commission can reach its "final decision." A staff report summarizing the rulemaking record and making initial recommendations to the Commission will be published later this year. The Presiding Officer's report will then be published a few weeks after publication of the staff report, followed by a mandatory sixty-day public comment period on those reports. Shortly thereafter, staff will forward its summary of the public comments and final recommendations to the Commission. After its consideration of the record, which may include presentation of oral argument by various interested parties, the Commission will vote on the recommendations. If the Commission votes to leave the Rule in place unchanged and terminate the proceeding, it will have made its "final decision" at that point. If, however, the Commission votes to amend or repeal the rule, staff will then have to draft and forward to the Commission a statement of basis and purpose explaining the Commission's decision. The Commission will then reach its "final decision" by voting to publish its statement of basis and purpose. Any schedule for completion of the amendment proceeding must take into account all of these possible decisions and procedural requirements, because the Commission can not and does not at this juncture presume to know what recommendations it will receive nor what decision it will ultimately make regarding amendment or repeal of the Rule. Taking all these factors into account, the Commission has determined that it is impractical to attempt to reach a "final decision" in this important matter by November 30, 1989—the current deadline required by § 453.10. The Commission has further determined that the proceeding raises important issues that can be resolved expeditiously without establishing a specific deadline for Commission action, and has directed its staff to act accordingly in completing and forwarding the rulemaking record to the Commission.

Accordingly, the Commission has determined to amend § 453.10 by rescinding the time limit for final Commission action concerning the rulemaking amendment proceeding to review the Funeral Rule. The Commission intends to reach a final decision expeditiously without establishing a fixed schedule.

List of Subjects in 16 CFR Part 453

Funeral homes, Price disclosure, Trade practices.

16 CFR Part 453 is amended as follows:

PART 453—FUNERAL INDUSTRY PRACTICES

1. The authority for Part 453 continues to read as follows:

> **Authority:** Sec. 6(g) 38 stat. 721 (15 U.S.C. 46(g)); 80 stat. 383, as amended, 81 stat. 54 (5 U.S.C. 552).

2. Section 453.10 is revised to read as follows:

§ 453.10 Mandatory review.

No later than four years after the effective date of this rule, the Commission shall initiate a rulemaking amendment proceeding pursuant to section 18 (d)(2)(b) of the FTC Act to determine whether the rule should be amended or terminated.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 89-10778 Filed 5-4-89; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket Nos. 79F-0058 and 83F-0087]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with a mixture of *N*-methyldiethanolamine and dimethylolpropionic acid. The polyurethane resin is to be used as a sizing agent in the manufacture of paper and paperboard in contact with aqueous and fatty foods. This action responds to two petitions filed by Akzo Chemicals, Inc. (at that time, the Armak Co.).

DATES: Effective May 5, 1989; written objections and requests for a hearing by June 5, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 30, 1979 (44 FR 19029), FDA announced that a petition (FAP 8B3371) had been filed by Akzo Chemicals, Inc. (at that time, the Armak Co.), 300 South Wacker Dr., Chicago, IL 60606, proposing that § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) be amended to provide for the safe use of an anionic polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with not more than 10 mole percent *N*-methyldiethanolamine and not less than

90 mole percent dimethylolpropionic acid.

In another notice, published in the **Federal Register** of April 12, 1983 (48 FR 15716), FDA announced that a petition (FAP 8B3370) had been filed by Akzo Chemicals, Inc. (at that time, the Armak Co.), 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 an anionic polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with a mixture of *N*-methyldiethanolamine and dimethylolpropionic acid.

FDA notes that although the petitioner's description of the production of the polyurethane additive varies slightly between these filing notices, the additive is, in both cases, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with not more than 10 mole percent *N*-methyldiethanolamine and not less than 90 mole percent dimethylolpropionic acid. Both petitions also request use of the additive as a sizing agent in the manufacture of paper and paperboard. The agency has therefore combined its review of these petitions in this final rule. FDA also notes that it is unnecessary to list this additive in § 176.180 because use of the additive in § 176.170 authorizes its use by cross-reference for the conditions of use in § 176.180.

FDA in its evaluation of the safety of this additive has reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although the polyurethane additive itself has not been found to cause cancer, it has been found to contain minute amounts of 2,4-toluenediamine and dibutyltin diacetate as byproducts of its production. These impurities have been shown to cause cancer in test animals and may be expected to be present at very low levels in the additive. Residual amounts of reactants and manufacturing aids, such as toluenediamine and dibutyltin diacetate, are commonly found as contaminants in chemical products, including food additives.

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 Food Additives Amendment (section 409(c)(3)(A) of the Act (21 U.S.C. 348 (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 has 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 had 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 United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimated the daily intake of the polyurethane produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with a mixture of *N*-methyldiethanolamine and dimethylolpropionic acid on the basis of several factors, including the migration of the additive under the most severe intended conditions of use and the probable concentration of the additive in the daily diet from food-contact articles that contain this substance. The estimated daily dietary exposure to the polyurethane low molecular weight fractions of the additive that are expected to migrate to food is 6.8 micrograms per day (2.3 parts per billion in the diet) for a 60-kilogram person.

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 here. However, the agency has reviewed available data from acute toxicity studies and subchronic studies on the additive. No adverse effects were reported in these studies. Because the polyurethane produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluenediisocyanate with a mixture of *N*-methyldiethanolamine and dimethylolpropionic acid has not been shown to cause cancer, the anticancer clause 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 chemicals that may be present as impurities 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 and 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure for humans.

A. 2,4-Toluenediamine

Although 2,4-toluenediisocyanate is one of the starting materials used in the manufacture of the polyurethane sizing agent, any unreacted 2,4-toluenediisocyanate would be hydrolyzed to 2,4-toluenediamine. Therefore, the agency's risk assessment was carried out only for 2,4-toluenediamine.

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive, as well as the level of 2,4-toluenediamine that may be present in the additive, FDA estimated the hypothetical worst-case exposure to 2,4-toluenediamine from the use of the additive in paper and paperboard to be 0.0038 parts per billion in the diet or 11.4 nanograms per person per day (Ref. 3). The agency used data from a National Cancer Institute (NCI) carcinogenesis bioassay (Ref. 4) on 2,4-toluenediamine fed to Fischer 344 rats and hybrid B6C3F1 mice to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of this polyurethane. The results of the bioassay demonstrated that the material was carcinogenic for female rats under the conditions of the study, inducing neoplasms of the liver and mammary gland.

FDA reviewed the bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 2,4-toluenediamine. The agency further concluded that an estimate of the upper bound level of lifetime human risk from potential exposure to 2,4-toluenediamine stemming from the proposed use of the polyurethane could be calculated from the bioassay. The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses 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, to a reasonable certainty, whether any harm will result from the proposed conditions and levels of use of the food additives.

Based on a worst-case exposure of 11.4 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from the potential exposure to 2,4-toluenediamine resulting from the use of the additive is 4×10^{-8}, or less than 1 in 25 million (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 2,4-toluenediamine is expected to be substantially less than the estimated daily intake. Therefore, the calculated upper bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to 2,4-toluenediamine that might result from the proposed use of the additive.

B. Dibutyltin Diacetate

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive, as well as the level of dibutyltin diacetate that may be present in the additive (Ref. 3), FDA also estimated the hypothetical worst-case exposure to dibutyltin diacetate from the use of this additive to be 0.0023 parts per trillion in the diet, or 0.069 nanograms per person per day. The agency used data in an NCI carcinogenesis bioassay on dibutyltin diacetate in which dibutyltin diacetate was fed to rats and mice (Ref. 6) to estimate the upper bound level of lifetime human risk from exposure to this chemical, stemming from the proposed use of this additive. The results of the bioassay on dibutyltin diacetate were found by FDA, in its review in 1979, to demonstrate that the material was carcinogenic for male and female mice under the conditions of the study. The test material caused an increased incidence of hepatocellular adenomas of both male and female mouse livers.

The agency recently reevaluated this bioassay and concluded that the available information on dibutyltin diacetate supports the agency's finding in 1979 of the carcinogenicity of this substance (Ref. 7). The agency further concluded that the NCI bioassay provided the appropriate basis on which to calculate an estimate of the upper bound limit of lifetime risk from potential exposure to dibutyltin diacetate stemming from the proposed use of the additive.

Based on a worst-case exposure of 0.069 nanograms per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to dibutyltin diacetate from the use of the polyurethane resin is 1.6×10^{-11}, or less than 2 in 100 billion (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to dibutyltin diacetate is expected to be substantially less than the estimated daily intake. Therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to dibutyltin diacetate that might result from the proposed use of the additive.

C. Needs for Specifications

The agency has also considered whether specifications are necessary to control the amounts of dibutyltin diacetate and 2,4-toluenediamine in the resin. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which dibutyltin diacetate and 2,4-toluenediamine may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper bound limit of lifetime risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 2 in 100 billion for dibutyltin diacetate and less than 1 in 25 million for 2,4-toluenediamine.

D. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe, and that the regulation 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.

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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 5, 1989 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.

IV. 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., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology," presented at the Second International Conference on Safety Evaluation and Regulation of Chemicals, October 24, 1983, Cambridge, MA.

3. Memorandum from Food & Color Additives Review Section to Indirect Additives Branch, dated March 10, 1988. "Cumulative Exposure Estimates for Toluenediisocyanate, 2,4-Toluenediamine, Aniline, and Dibutyltin Diacetate. DFCA memorandum of 8-26-87."

4. "Bioassay of 2,4-Diaminotoluene for Possible Carcinogenicity," National Cancer Institute, NTP Technical Report No. 162, 1979.

5. Report of the Quantitative Risk Assessment Committee. "Upper Bound Risk for 2,4-Toluenediamine (TDA) and Dibutyltin Diacetate in FAP's 8B3370 and 8B3371," July 28, 1988.

6. "Bioassay of Dibutyltin Diacetate for Possible Carcinogenicity," National Cancer Institute, NTP Technical Report No. 183, 1979.

7. Memorandum of Conference, Cancer Assessment Committee, February 1, 1989, "Dibutyltin Diacetate".

List of Subjects in 21 CFR Part 176

Food additives, Food packaging, Paper and paperboard.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part I76 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(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 176.170 is amended in paragraph (a)(5) by alphabetically adding a new entry in the table to read as follows:

§ 176. 170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * *	
Anionic polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and 2,4-toluenediisocyanate with not more than 10 mole percent *N*-methyldiethanolamine and not less than 90 mole percent dimethylolpropionic acid. The final product is a 15 to 20 percent by weight aqueous solution, having a Brookfield viscosity of 25 to 100 centipoises at 24 °C (75 °F).	For use only as a surface sizing agent at a level not to exceed 0.1 percent by weight of dry paper and paperboard.
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Dated: April 27, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-10761 Filed 5-4-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[T.D. 8249]

RIN 1545-AK21

Minimum Tax—Tax Benefit Rule

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the application of the tax benefit rule to the minimum tax. Changes to the applicable law were made by the Tax Reform Act of 1976. The regulations provide taxpayers with guidance necessary to determine the amount of tax preference items that do not provide a current tax benefit because of available credits and, therefore, are not subject to minimum tax. The text of the temporary regulations set forth in this document also serves as the text of the proposed regulations cross-referenced in the Notice of Proposed Rulemaking in the Proposed Rules section of this issue of the Federal Register.

DATES: Except as otherwise provided, the amendments are effective for items of tax preference that are subject to the minimum tax imposed by section 56 of the Code and arise in taxable years beginning after December 31, 1975, and before January 1, 1987.

FOR FURTHER INFORMATION CONTACT: William A. Jackson, 202-566-4196, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information requirements contained in this regulation have been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number 1545-1093. The estimated annual burden per respondent or recordkeeper varies from 10 minutes to 14 minutes, depending on individual circumstances, with an estimated average of 12 minutes.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual