a death after December 1972, and for establishing a period of disability.

* * * * *

(e) *Certification of internment.* The certification concerning the internment is made by the Archivist of the United States or his or her representative. After the internment has been verified, wages are deemed to have been paid to the internee.

6. The authority citation for Subpart N continues to read as follows:

Authority: Secs. 205 (a) and (p), 210 (l) and (m), 215(b), 217, 229 and 1102 of the Social Security Act; 42 U.S.C. 405 (a) and (p), 410 (l) and (m), 415(h), 417, 429 and 1302.

7. Section 404.1341 is amended by revising paragraphs (a) and (c) and by adding paragraph (d) as set forth:

§ 404.1341 Wage credits for a member of a uniformed service.

(a) *General.* In determining your entitlement to, and the amount of your monthly benefit (or lump sum death payment) based on your wages while on active duty as a member of the uniformed service after 1956, and for establishing a period of disability as discussed in § 404.132, we add wage credits to the wages paid you as a member of that service. The amount of the wage credits, the applicable time periods, the wage credit amount limits, and the requirement of a minimum period of active duty service for granting these wage credits, are discussed in paragraphs (b), (c), and (d) of this section.

* * * * *

(c) *Limits on wage credits.* The amount of these wage credits cannot exceed—

(1) $1200 for any calendar year, or

(2) An amount which when added to other earnings causes the total earnings for the year to exceed the annual earnings limitation explained in §§ 404.1047 and 404.1096(b).

(d) *Minimum active-duty service requirement.* (1) If you enlisted for the first time in a regular component of the Armed Forces on or after September 8, 1980, you must complete the shorter of 24 months of continuous active duty or the full period that you were called to active duty to receive these wage credits, unless:

(i) You are discharged or released from active duty for the convenience of the government in accordance with section 1171 of Title 10 of the U.S. Code or because of hardship as specified in section 1173 of Title 10 of the U.S. Code;

(ii) You are discharged or released from active duty for a disability incurred or aggravated in line of duty;

(iii) You are entitled to compensation for service-connected disability or death under Chapter 11 of Title 38 of the U.S. Code;

(iv) You die during your period of enlistment; or

(v) *You were discharged prior to October 14, 1982,* and your discharge was—

(A) Under Chapter 61 of Title 10 of the U.S. Code; or

(B) Because of a disability which resulted from an injury or disease incurred in or aggravated during your enlistment which was not the result of your intentional misconduct and did not occur during a period of unauthorized absence.

(2) If you entered on active duty as a member of the uniformed services as defined in § 404.1330 *on or after* October 14, 1982, having neither previously completed a period of 24 months' active duty nor been discharged or released from this period of active duty under section 1171, Title 10 of the U.S. Code (i.e., convenience of the government), you must complete the shorter of 24 months of continuous active duty or the full period you were called or ordered to active duty to receive these wage credits, unless:

(i) You are discharged or released from active duty for the convenience of the government in accordance with section 1171 of Title 10 of the U.S. Code or because of hardship as specified in section 1173 of Title 10 of the U.S. Code;

(ii) You are discharged or released from active duty for a disability incurred or aggravated in line of duty;

(iii) You are entitled to compensation for service-connected disability or death under Chapter 11 of Title 38 of the U.S. Code; or

(iv) You die during your period of active service.

[FR Doc. 87-18088 Filed 8-10-87; 8:45 am]
BILLING CODE 4190-11-M

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Devices and Radiological Health

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on exemption of electronic products from performance standards for electronic products and on granting and withdrawing variances from these standards. This amendment delegates authority to make decisions on exemptions and variances to the Director and Deputy Director of the Office of Compliance and to the Director and Deputy Director of the Office of Standards and Regulations in the Center for Devices and Radiological Health (CDRH). This redelegation of authority will expedite the handling of requests for variances and exemptions by decentralizing the approval of actions to the decisionmaking level.

EFFECTIVE DATE: August 11, 1987.

FOR FURTHER INFORMATION CONTACT: Marjorie J. Shandruk, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending § 5.86 *Variances from performance standards for electronic products* (21 CFR 5.86) and § 5.87 *Exemption of electronic products from performance standards and prohibited acts* (21 CFR 5.87) by adding to the list of delegates the Director and Deputy Director, Office of Compliance, and the Director and Deputy Director, Office of Standards and Regulations, Center for Devices and Radiological Health.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR Part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552; 7 U.S.C. 2217; 15 U.S.C. 638, 1451 *et seq.*; 21 U.S.C. 41 *et seq.*, 61-63, 141 *et seq.*, 301-392, 467f(b), 679(b), 801 *et seq.*, 823(f), 1031 *et seq.*; 35 U.S.C. 156; 42 U.S.C. 219, 241, 242(a), 242a, 242l, 242o, 243, 262, 263, 263b through 263m, 264, 265, 300u *et seq.*, 1395y and 1395y note, 3246b(b)(3), 4831(a), 10007, and 10008; Federal Caustic Poison Act (44 Stat. 1406); Federal Advisory Committee Act (Pub. L. 92-463); E.O. 11490, 11921.

2. Part 5 is amended by revising §§ 5.86 and 5.87 to read as follows:

§ 5.86 Variances from performance standards for electronic products.

The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in Subchapter J of this chapter:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

§ 5.87 Exemption of electronic products from performance standards and prohibited acts.

The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act (the act) and to exempt an electronic product or class of products from all or part of the provisions of section 360B(a) of the act under section 360B(b) of that act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

Dated: July 31, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-18145 Filed 8-10-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 73

[Docket No. 86C-0495]

Mica; Addition of Listing for Use in Dentifrices That are Drugs as Well as Cosmetics; Change in Specification for Fineness

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of mica in dentifrices that are drugs as well as cosmetics and is changing the fineness specification for mica to permit a larger average particle size distribution. This action responds to a petition filed by the Procter & Gamble Co.

DATES: Effective September 11, 1987. Except as to any provisions that may be stayed by the filing of proper objections; objections by September 10, 1987.

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: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 3, 1987 (52 FR 3349), FDA announced that a color additive petition (CAP 7C0207) had been filed by the Procter & Gamble Co., Cincinnati, OH 45241, proposing that § 73.1496 (21 CFR 73.1496) be amended to provide for the safe use of mica ($K_2Al_4(Al_2S_6O_{20})(OH)_4$ or, alternatively, $H_2KAl_3(SiO_4)_3$) in dentifrices that are drugs as well as cosmetics. The petitioner also proposed a change in the fineness specification for mica to permit, but not require, a larger average particle size distribution. The purpose of the change in fineness is to increase the versatility of mica as a pearlescent color additive. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

FDA has evaluated the data in the petition and data supporting the previous regulations involving this color additive. In support of its claim that mica is safe for use in dentifrices that are drugs as well as cosmetics, the petitioner submitted references to a number of animal toxicity studies for the color additive. These animal studies were previously used to support the safety of the currently permitted use of mica (21 CFR 73.1496 and 73.2496). The studies include an acute oral toxicity study in rats, an acute eye application study in rabbits, an acute dermal application study in rabbits, a subchronic eye irritation study in rabbits, and a 4-week dermal evaluation in rabbits. These studies did not reveal evidence of local or systemic toxic effects from the administration of mica under these experimental conditions of use. On the basis of these studies, the agency concludes that the use of mica that complies with the new fineness specification in dentifrices that are drugs as well as cosmetics is safe.

The petitioner has also requested a change in fineness specification to allow for the use of a larger average particle size by dropping the requirement that 80 percent pass through a 200-mesh sieve. The agency has determined that this change will have no effect on the safety of the color additive because an increase in particle size would only serve to inhibit the potential absorption of mica from the gastrointestinal tract and therefore reduce the potential for systemic adverse effects. Consequently, this change in particle size will not make the use of this color any less safe than its use in the curently regulated form, and FDA is amending § 73.1496 as set forth below.

Because one of the chemical formulas for mica (potassium aluminum silicate) set forth in § 73.1496(a) was inadvertently represented as $K_2Al_4(Al_2Si_6O_{20})(OH_4)$, the agency is correcting that formula in the regulation to read "$K_2Al_4(Al_2Si_6O_{20})(OH)_4$."

In accordance with § 71.15 (21 CFR 71.15), 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 (address above) by appointment with the information contact person listed above. As provided in § 71.15, 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 and 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before September 10, 1987, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR Part 73 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. In § 73.1496 by revising the entry for "Identity" in paragraph (a)(1), "Specifications" in paragraph (b), and "Uses and restrictions" in paragraph (c) to read as follows:

§ 73.1496 Mica.

(a) *Identity.* (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate, $K_2Al_4(Al_2Si_6O_{20})(OH)_4$ or, alternatively, $H_2KAl_3(SiO_4)_3$. Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

* * * * *

(b) *Specifications.* Mica shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 100-mesh sieve.

Loss on ignition at 600–650 °C, not more than 2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

* * * * *

Dated: August 5, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–18206 Filed 8–10–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 176

[Docket No. 79F–0469]

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 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. This action responds to a food additive petition filed by International Minerals & Chemical Corp. The petition was subsequently transferred to Angus Chemical Co.

DATES: Effective August 11, 1987; objections by September 10, 1987.

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

FOR FURTHER INFORMATION CONTACT: Kenneth J. Falci, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of January 25, 1980 (45 FR 6174), FDA announced that a food additive petition (FAP 0B3486) had been filed by International Minerals & Chemical Corp., P.O. Box 207, Terre Haute, IN 47808. Responsibility for the petition was subsequently transferred to Angus Chemical Co., 2211 Sanders Rd., Northbrook, IL 60062. The petition proposed that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 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 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.

FDA, in its evaluation of the safety of this additive, 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 minute amounts of 2-nitropropane as a byproduct of its production. That chemical, 2-nitropropane, has been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as this chemical, are commonly found as contaminants in chemical products, including food additives.

The agency published a proposal in the Federal Register of December 1, 1978 (43 FR 56247), to amend 21 CFR 175.105 by deleting the provision for the food additive use of 2-nitropropane as a component of adhesives intended for use in food packaging and to list the additive as a substance prohibited from addition to human food in 21 CFR Part 189. The agency intends to take further action on this proposal at a future date.

FDA's evaluation of any risks created by the presence of 2-nitropropane as an impurity is based on different considerations than its evaluation of the safety of the use of this chemical as a food additive, however. Therefore, FDA concludes that it can proceed with this rulemaking independently of the latter evaluation.

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 not itself 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 estimates that the petitioned use of 2-amino-2-methyl-1-propanol in paper and paperboard products that contact dry food and fatty food will result in levels of exposure to this additive that are quite small. 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. Because 2-amino-2-methyl-1-propanol has not been shown to cause cancer, the anticancer clause does not apply to it.

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 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 it 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, 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 levels of 2-nitropropane that may be present in the additive (Ref. 3), FDA estimated the hypothetical worst case exposure to 2-nitropropane from the use of this additive in pigmented coatings contacting dry food and fatty food to be 1.0 nanogram per person per day. The agency used data in three carcinogenic bioassays on 2-nitropropane 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. 4 through 7). The results of the bioassays on 2-nitropropane demonstrated that the material was carcinogenic for 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. 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 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 additive.

Based on a worst case exposure of 1.0 nanogram per person per day, 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 is 6×10^{-10} or less than 1 in 1 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual 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. 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.

B. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the 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 small levels; and (2) the upper bound limit of lifetime risk from exposure to this impurity, even under worst case assumptions, is very low, less than 1 in 1 billion.

C. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed uses for the additive in paper and paperboard

products in contact with dry food and fatty food are safe, and that § 176.170 should be amended as set forth below.

FDA also concludes that listing of the additive in § 176.180 *Components of paper and paperboard in contact with dry food* is not necessary and would be redundant because this section provides by cross-reference for the use of ingredients listed in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* for dry-food contact. Therefore, this final rule only lists the additive in § 176.170.

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 (address above) 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 and 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).

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, p. 59, July 1979.

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

3. Memorandum dated September 25, 1985, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "FAP OB3486—International Minerals and Chemical Corporation— Exposure to 2-Nitropropane."

4. 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.

5. Griffin, T.B., F. Coulston, and A.A. Stein, "Chronic Inhalation Exposure of Rats to Vapors of 2-Nitropropane at 22 ppm," *Ecotoxicology Environmental Safety*, 4:267–281, 1980.

6. 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.

7. Lewis, T.R., C.E. Ulrich, and W.M. Busey, "Subchronic Inhalation Toxicity of Nitromethane and 2-Nitropropane," *Journal of Environmental Pathology and Toxicology*, 2:233–249, 1979.

Objections

Any person who will be adversely affected by this regulation may at any time on or before September 10, 1987 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 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 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(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 176.170(a)(5) by alphabetically inserting a new item in the list of substances 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 suspensions 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 in contact only with food of the types identified in paragraph (c) of this section, Table 1, under types V, VIII, and IX and under conditions of use described in paragraph (c) of this section, Table 2, conditions of use E through G.
* * * * *	

Dated: August 4, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–18142 Filed 8–10–87; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 177

[Docket No. 86F-0412]

Indirect Food Additives; Polymers

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 the cross-linked polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride and piperazine as a reverse osmosis membrane intended for use in contact with food. This action responds to a petition filed by FilmTec Corp.

DATES: Effective August 11, 1987; objections by September 10, 1987.

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

FOR FURTHER INFORMATION CONTACT: Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 31, 1986 (51 FR 47311), FDA announced that a petition (FAP 6B3904) had been filed by FilmTec Corp., 7200 Ohms Lane, Minneapolis, MN 55435, proposing that § 177.2550 *Reverse osmosis membranes* (21 CFR 177.2550) be amended to provide for the safe use of cross-linked polyamide prepared by the polymerization of 1,3,5-benzenetricarbonyl trichloride with piperazine as a reverse osmosis membrane intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that 21 CFR 177.2550(a) 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 (address above) 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 and 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before September 10, 1987, 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 177

Food additives, Food packaging.

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, Part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR Part 177 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 177.2550 is amended by revising paragraph (a) to read as follows:

§ 177.2550 Reverse osmosis membranes.

* * * * *

(a) *Identity.* For the purpose of this section, the reverse osmosis membrane consists of a cross-linked high molecular weight polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride with 1,3-benzenediamine (CAS Reg. No. 63044–99–9) or piperazine (CAS Reg. No. 110–85–0). The membrane is on the food-contact surface, and its maximum weight is 62 milligrams per square decimeter (4 milligrams per square inch) as a thin film composite on a suitable support.

* * * * *

Dated: August 3, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–18143 Filed 8–10–87; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[T.D. 8149]

Income Tax; Taxable Years Beginning After December 31, 1986; OMB Control Numbers Under the Paperwork Reduction Act; Limitation on Corporate Net Operating Loss Carryforwards

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to corporate ownership changes and the limitation on corporate net operating loss carryforwards under section 382 of the Internal Revenue Code of 1986 ("Code"). The temporary regulations provide guidance relating to the section 382 limitation on corporate net operating loss carryforwards when there is an ownership change within the meaning of section 382. 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: The temporary regulations are effective August 11, 1987, and apply generally to any ownership change, within the meaning of section 382, occurring after December 31, 1986.

FOR FURTHER INFORMATION CONTACT: Keith E. Stanley of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 (Attention: CC:LR:T) or telephone (202) 566–3458 (not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

This document provides temporary regulations to be added to the Income Tax Regulations (26 CFR Part 1) under section 382 of the Internal Revenue Code of 1986. The temporary regulations provide guidance regarding the section 382 limitation on corporate net operating