material in an industry product is leather or other material. This includes, among other practices, the use of a stamp, tag, label, card, or other device in the shape of a tanned hide or skin or in the shape of a silhouette of an animal, in connection with any industry product that has the appearance of leather but that is not made wholly or in substantial part from animal skin or hide.

(e) *Misrepresentation that product is wholly of a particular composition.* A misrepresentation should not be made, directly or by implication, that an industry product is made wholly of a particular composition. A representation as to the composition of a particular part of a product should clearly indicate the part to which the representation applies.[2] Where a product is made principally of leather but has certain non-leather parts that appear to be leather, the product may be described as made of leather so long as accompanied by clear disclosure of the non-leather parts. For example:

(1) An industry product made of top grain cowhide except for frame covering, gussets, and partitions that are made of plastic but have the appearance of leather may be described as: Top Grain Cowhide With Plastic Frame Covering, Gussets and Partitions; or Top Grain Cowhide With Gussets, Frame Covering and Partitions Made of Non-Leather Material.

(2) An industry product made throughout, except for hardware, of vinyl backed with cowhide may be described as: Vinyl Backed With Cowhide (See also disclosure provision concerning use of backing material in paragraph (c) of this section).

(3) An industry product made of top grain cowhide except for partitions and stay, which are made of plastic-coated fabric but have the appearance of leather, may be described as: Top Grain Cowhide With Partitions and Stay Made of Non-leather Material; or Top Grain Cowhide With Partitions and Stay Made of Plastic-Coated Fabric.

(f) *Ground, pulverized, shredded, reconstituted, or bonded leather.* A material in an industry product that contains ground, pulverized, shredded, reconstituted, or bonded leather and thus is not wholly the hide of an animal should not be represented, directly or by implication, as being leather. This provision does not preclude an accurate representation as to the ground, pulverized, shredded, reconstituted, or bonded leather content of the material. However, if the material appears to be leather, it should be accompanied by either:

(1) An adequate disclosure as described by paragraph (a) of this section; or

(2) If the terms ''ground leather,'' ''pulverized leather,'' ''shredded leather,'' ''reconstituted leather,'' or ''bonded leather'' are used, a disclosure of the percentage of leather fibers and the percentage of non-leather substances contained in the material. For example: An industry product made of a composition material consisting of 60% shredded leather fibers may be described as: Bonded Leather Containing 60% Leather Fibers and 40% Non-leather Substances.

(g) *Form of disclosures under this section.* All disclosures described in this section should appear in the form of a stamping on the product, or on a tag, label, or card attached to the product, and should be affixed so as to remain on or attached to the product until received by the consumer purchaser. All such disclosures should also appear in all advertising of such products irrespective of the media used whenever statements, representations, or depictions appear in such advertising which, absent such disclosures, serve to create a false impression that the products, or parts thereof, are of a certain kind of composition. The disclosures affixed to products and made in advertising should be of such conspicuousness and clarity as to be noted by purchasers and prospective purchasers casually inspecting the products or casually reading, or listening to, such advertising. A disclosure necessitated by a particular representation should be in close conjunction with the representation.

§ 24.3 Misuse of the terms ''waterproof,'' ''dustproof,'' ''warpproof,'' ''scuffproof,'' ''scratchproof,'' ''scuff resistant,'' and ''scratch resistant.''

It is unfair or deceptive to:

(a) Use the term ''Waterproof'' to describe all or part of an industry product unless the designated product or material prevents water from contact with its contents under normal conditions of intended use during the anticipated life of the product or material.

(b) Use the term ''Dustproof'' to describe an industry product unless the product is so constructed that when it is closed dust cannot enter it.

(c) Use the term ''Warpproof'' to describe all or part of an industry product unless the designated product or part is such that it cannot warp.

(d) Use the term ''Scuffproof,'' ''Scratchproof,'' or other terms indicating that the product is not subject to wear in any other respect, to describe an industry product unless the outside surface of the product is immune to scratches or scuff marks, or is not subject to wear as represented.

(e) Use the term ''Scuff Resistant,'' ''Scratch Resistant,'' or other terms indicating that the product is resistant to wear in any other respect, unless there is a basis for the representation and the outside surface of the product is meaningfully and significantly resistant to scuffing, scratches, or to wear as represented.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–25358 Filed 10–2–96; 8:45 am]

BILLING CODE 6750–01–P

[2] With regard to footwear, it is sufficient to disclose the presence of non-leather materials in the upper, the lining and sock, or the outersole, provided that the disclosure is made according to predominance of materials. For example, if the majority of the upper is composed of manmade material: Upper of manmade materials and leather.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 91C–0189]

Listing of Color Additives for Coloring Contact Lenses; 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of the colored reaction products formed by copolymerizing 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester either with glyceryl methacrylate/methyl methacrylate/ethylene glycol dimethacrylate monomers or with *N, N*-dimethyl acrylamide/methyl methacrylate/ethylene glycol dimethacrylate monomers to form contact lenses. This action is in response to a petition filed by Sola/Barnes-Hind.

DATES: Effective November 5, 1996, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by November 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration,

12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of June 14, 1991 (56 FR 27518), FDA announced that a color additive petition (CAP 0C0226) had been filed by Sola/Barnes-Hind (now Pilkington Barnes Hind), 810 Kifer Rd., Sunnyvale, CA 94086–5200. The petition proposed that the color additive regulations be amended in 21 CFR part 73 to provide for the safe use of 1,4-bis[(2-methacryloxyethylamino)-9,10-anthraquinone to color contact lenses prepared with glyceryl methacrylate/methyl methacrylate/ethylene glycol dimethacrylate copolymer and *N, N*-dimethyl acrylamide/methyl methacrylate/ethylene glycol dimethacrylate copolymer. The petition was filed under section 706(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376(d)(1)), presently section 721(d)(1) of the act (21 U.S.C. 379e(d)(1)). The agency has subsequently determined that 1,4-bis[(2-methacryloxyethylamino)-9,10-anthraquinone is more appropriately identified as 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester and that the color additives are the colored reaction products formed by copolymerizing 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers.

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 379e(a)). The use of the reaction products of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers as color additives in manufacturing contact lenses is subject to this listing requirement. The color additives are formed into contact lenses in such a way that at least some of the color additives will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additives will be in direct contact with the body for a significant period of time. Consequently, the use of the color additives currently before the agency is subject to the statutory listing requirement.

III. Identity

The color additives are produced by copolymerizing 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561–07–1) either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, ethylene glycol dimethacrylate monomers. The resulting copolymeric product is formed into a contact lens.

IV. Safety Evaluation

The agency believes that because 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester has a significantly lower molecular weight than the subject copolymer, it would be the compound most likely to migrate out of the lens into the ocular fluid and would also be more readily absorbed into the body than the subject copolymer and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additives focused on exposure to unreacted 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester.

FDA concludes, from the data submitted in the petition and from other relevant information, that the average daily exposure to 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester from these petitioned uses in contact lenses would be no greater than 0.61 nanograms per person per day (ng/p/d). The agency-calculated upper limit was based on two factors. First, the maximum use level anticipated by the petitioner is 140 parts per million (ppm) of the lens material or 11 micrograms (µg) of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester per contact lens (Ref. 1). Second, the agency made two assumptions: (1) The user will replace these lenses once each year with a new pair of identical lenses; and (2) one percent of the 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester will migrate from the lenses into the eyes over the 1-year period (Ref. 2). Because these assumptions are conservative estimates, exposure to 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester from these uses is likely to be less than 0.61 ng/p/d (Ref. 2).

To establish the safety of the subject additive, the petitioner conducted toxicity studies with 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester, colored lenses, and colored lens extracts. Studies submitted included 27 in vitro cytotoxicity studies: 4 by the inhibition of cell growth method (with lens extracts and 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester), 4 by the agar overlay method (with lens), and 19 by the direct-contact method using mouse fibroblast cells (with lens, lens extracts and neat 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester). Both the lenses and lens extracts were found to be noncytotoxic to mouse fibroblast cells. In addition, two guinea pig maximization studies (Magnusson and Kligman) with lens extracts, two 72-hour ocular irritation studies with lens extracts in rabbits, one intracutaneous skin reaction test with lens extracts in rabbits, two acute systemic toxicity tests with lens extracts in mice, and four ocular irritation studies with lenses in rabbits were submitted. The most relevant tests for a color that is bound covalently to a contact lens are those that compare colored to noncolored lenses in the rabbit ocular irritation tests. These studies demonstrated no evidence of ocular irritation or an allergic response in the test animals. The maximum nontoxic concentration for 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester was determined to be 140 µg/milliliter (mL) by the ocular irritation tests.

To relate the 140 µg/mL nontoxic level, established in the ocular irritation tests, to the 0.61 ng/p/d exposure from wearing the colored lenses, the agency calculated the maximum concentration level of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure to 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester in each eye would be 0.30 ng and that

this would be diluted by the average daily tear film of 1.2 mL produced in each eye. This concentration is equal to a maximum daily concentration in the tear flow of the eye of 0.25 ng/mL, and represents a more than a 55,000 fold safety factor for this proposed use of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester, when compared to the non-toxic level established in the ocular irritation test.

Based upon the available toxicity data, the small amount of 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester used to form the color additive in the contact lenses, and the agency's exposure calculation for 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester, FDA finds that the reaction products formed by copolymerizing 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers are safe for use as color additives in contact lenses. FDA further concludes that the safety margin is sufficiently large that no limitation is required beyond the usual limitation that reactants may be used in amounts not to exceed the minimum reasonably required to accomplish the intended technical effect. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of the reaction products formed by copolymerizing 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, ethylene glycol dimethacrylate monomers to form colored contact lenses, and that the color additives are safe and suitable for their intended use.

VI. Inspection of Documents

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 under the ''For Further Information Contact'' section of this document. 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.

VII. 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.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 4, 1996, 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.

IX. 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. Memorandum from the Chemistry Review Branch to the Indirect Additives Branch, ''CAP 0C0226 (MATS# 494, M2.3, 2.4, and 2.5): Sola Barnes Hind submissions dated 8–19–92, 10–5–92, and 1–25–93. BMAQ as a colorant in contact lenses,'' dated June 28, 1993.

2. Memorandum of meeting dated August 19, 1994.

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, 21 CFR 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. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. Section 73.3100 is added to subpart D to read as follows:

§ 73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.

(a) *Identity.* The color additives are 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561–07–1) copolymerized either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N, N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens made from the color additives.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health and therefore the color

additives are exempt from the certification requirements of section 721(c) of the act.

Dated: September 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25261 Filed 10–2–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 95F–0175]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the safe use of sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: Effective October 3, 1996; written objections and requests for a hearing by November 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John R. Bryce, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3023.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 13, 1995 (60 FR 36149), FDA announced that a food additive petition (FAP 5B4458) had been filed by Asahi Denka Kogyo K.K., c/o Japan Technical Information Center, Inc., 775 South 23d St., Arlington, VA 22202. The petition proposed to amend § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) of the food additive regulations to provide for the safe use of sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food under conditions of use A and B as described in Table 2 of 21 CFR 176.170(c).

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, and the additive will achieve its intended technical effect; therefore the regulations in § 178.3295 should be amended as set forth below.

FDA's review of the subject petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til, et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study,

''* * * that the data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical detail in the study, questionable histopathologic conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

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 § 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 November 4, 1996, 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.

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. Soffritti, M., C. Maltoni, F. Maffei, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, Vol. 5, No. 5:699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, Vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of Conference concerning ''Formaldehyde,'' Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

List of Subjects in 21 CFR Part 178

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 178 is amended as follows: