PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

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

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

2. Section 176.300 is amended by alphabetically adding a new entry to the table in paragraph (c) to read as follows:

§ 176.300 Slimicides.

* * * * *

(c) * * *

List of substances	Limitations
* * * * *	
Glutaraldehyde (CAS Reg. No. 111-30-8).	
* * * * *	

* * * * *

Dated: July 26, 1990.

Douglas L. Archer,

Acting Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-18193 Filed 8-3-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 177

[Docket No. 89F-0335]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for alternative specifications applicable to 4-methylpentene-1 copolymers for use as articles or components of articles intended for use in contact with food. This action is in response to a petition filed by Mitsui Petrochemical Industries, Ltd.

DATES: Effective August 6, 1990; written objections and requests for a hearing by September 5, 1990. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) of certain publications in 21 CFR 177.1520 (d)(8) and (d)(9), effective August 6, 1990.

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

FOR FURTHER INFORMATION CONTACT: Thomas C. Brown, 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 August 30, 1989 (54 FR 35939), FDA announced that a food additive petition (FAP 9B4160) had been filed by Mitsui Petrochemical Industries, Ltd., Kasumigaseki Bldg., P.O. Box 90, 2-5 Kasumigaseki 3-chome, Chiyoda-KU, Tokyo 100, Japan, proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide for alternate specifications applicable to 4-methylpentene-1 copolymers for use as articles or components of articles intended for use in contact with food. Alternate specifications in the table in § 177.1520(c), entry 3.3, would include:

(1) Lowering the minimum acceptable melting point from 235 to 220 °C as determined by the American Society for Testing Materials (ASTM) method D3418-82;

(2) Deleting the specification for maximum extractable fraction in *n*-hexane and maximum soluble fraction in xylene; and

(3) Establishing a specification for minimum intrinsic viscosity of 1.0, as determined by ASTM method D1601-78.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed specifications for 4-methylpentene-1 copolymers are appropriate as alternative specifications to those currently in the regulation. Therefore, the agency is amending § 177.1520 in the table in paragraph (c) by revising entry 3.3 and adding paragraphs (d)(8) and (d)(9) 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 determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before September 5, 1990 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, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR 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, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 177.1520 is amended in the table in paragraph (c) by revising entry 3.3 and by adding new paragraphs (d)(8) and (d)(9) to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(c) * * *

Olefin polymers	Density	Melting point (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
* * * *	*	*	*	
3.3a Olefin polymers described in paragraph (a)(3)(ii) of this section	0.82–0.85	MP: 235–250 °C	6.6 pct at reflux	7.5 pct at 25 °C.
3.3b Olefin copolymers described in paragraph (a)(3)(ii) of this section, provided that such olefin polymers have a melt temperature of 220 °C to 250 °C (428 °F to 482 °F) as determined by the method described in paragraph (d)(8) of this section and minimum intrinsic viscosity of 1.0 as determined in paragraph (d)(9) of this section.	0.82–0.85			
* * * *	*	*	*	

(d) * * *

(8) *Melting peak temperature.* The melt temperature of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 3418–82, "Standard Test Method for Transition Temperatures of Polymers by Thermal Analysis," which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(9) *Intrinsic viscosity.* The intrinsic viscosity of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 1601–78, "Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers," which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

* * * * *

Dated: July 26, 1990.

Douglas L. Archer,

Acting Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–18191 Filed 8–3–90; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 87F–0319]

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 provide for the safe use of 3,3'-[(2,5-dimethyl-1, 4-phenylene)bis[iminocarbonyl(2-hydroxy-3, 1-naphthalenediyl)azo]] bis(4-methylbenzoic acid), bis(2-chloroethyl) ester as a colorant for food-contact polymers. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective August 6, 1990; written objections and requests for a hearing by September 5, 1990.

ADDRESSES: 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: Hortense S. Macon, 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 November 9, 1987 (52 FR 43122), FDA announced that a food additive petition (FAP 7B4026) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 3,3'-[(2,5-dimethyl-1, 4-phenylene)bis[iminocarbonyl(2-hydroxy-3, 1-naphthalenediyl)azo]] bis(4-methylbenzoic acid), bis(2-chloroethyl) ester as a colorant for food-contact polymers.

FDA has evaluated data in the petition and other relevant material. The agency concludes that these data and material establish the safety of the level of use of the additive in the manufacture of polymers, and that the regulations should be amended in the table in § 178.3297(e) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before September 5, 1990, 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 anylysis 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 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 and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

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

2. Section 178.3297 is amended in the table is paragraph (e) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * * * *	
3,3'-[(2,5-Dimethyl-1,4-phenylene)bis[imino-carbonyl(2-hydroxy-3,1-naphthalenediyl) azo]] bis(4-methylbenzoic acid), bis(2-chloroethyl) ester (CAS Reg. No. 68259-05-2).	For use at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
* * * * *	

Dated: July 26, 1990.

Douglas L. Archer,

Acting Deputy Director, Center for Food Safety and Applied Nutrition

[FR Doc. 90-18192 Filed 8-3-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Certain Drug Combinations Involving Melengestrol Acetate, Monensin, Lasalocid, and Tylosin

AGENCY: Food and Drug Administration HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of six new animal drug applications (NADA's) filed by The Upjohn Co. The applications provide for use of separately approved Type A medicated articles containing melengestrol acetate, monensin, lasalocid, and tylosin to manufacture Type C medicated feeds containing certain combinations of these drugs. The feeds are for use in heifers confined for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus, and reduced incidence of liver abscesses. The regulations are further amended editorially to improve clarity and eliminate redundancies.

EFFECTIVE DATE: August 6, 1990.

FOR FURTHER INFORMATION CONTACT: Robert J. Condon, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, filed six NADA's providing for combining separately-approved melengestrol acetate (MGA), monensin sodium, lasalocid sodium, and tylosin phosphate Type A medicated articles to manufacture the following Type C medicated feeds:

(1) MGA from a dry (NADA 138-995) or liquid (NADA 138-192) Type A medicated article plus tylosin phosphate.

(2) MGA from a dry (NADA 138-792) or liquid (NADA 138-870) Type A medicated article, monensin sodium, and tylosin phosphate.

(3) MGA from a dry (NADA 138-904) or liquid (NADA 138-992) Type A medicated article, lasalocid sodium, and tylosin phosphate.

The feeds are intended for heifers confined for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses. The NADA's are approved and § 558.342 (21 CFR 558.342) is amended by adding new paragraphs (c)(4), (c)(5), and (c)(6) to reflect the approvals. The basis for the approval is discussed in the freedom of information summary.

Certain regulations are also amended for editorial reasons. Portions of the regulations in § 558.342 are amended to correct inconsistencies and to make them more easily understood while regulations in §§ 558.311 and 558.355 are removed because they are redundant. The regulation for MGA plus lasalocid sodium in § 558.311(e)(1)(xii), that is a repetition of a regulation in § 558.342(c)(3), is removed and replaced with a reference to the latter regulation in § 558.311(e)(3)(i). Similarly, the regulation for melengestrol acetate plus monensin in § 558.355(f)(3)(iv), that is a repetition of a regulation in § 558.342(c)(2), is removed and replaced with a reference to the latter regulation.

These are new animal drugs used in Type A medicated articles to make Type C medicated feeds. MGA is a Category II drug which, as provided in § 558.4, requires an approved form FDA 1900 for making a Type C medicated feed from a Type A medicated article. Therefore, an approved form FDA 1900 is required for making a Type C medicated feed containing melengestrol acetate in various combinations involving monensin, lasalocid, and tylosin as in the approved subject NADA's and in the regulations herein added to § 558.342.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

These approvals qualify for 3 years of marketing exclusivity beginning August 6, 1990, because the criteria for such exclusivity under the Generic Animal Drug and Patent Term Restoration Act of 1988, section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)) have been met.

The Agency has determined under § 25.24(d)(1)(ii) (21 CFR 25.24(d)(1)(ii)) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).