

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 a notice of the objections that the agency has received, or the 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, 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. New § 73.3106 is added to subpart D to read as follows:

#### § 73.3106 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone.

(a) *Identity.* The color additive is 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (CAS Reg. No. 121888-69-5). The color additive is copolymerized with hydroxyethyl methacrylate monomer to form the lens material.

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

(2) Authorization and compliance with this use 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 in which the color additive is used.

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

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: July 18, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-17312 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Parts 510 and 558

#### Animal Drugs, Feeds, and Related Products; Tylosin, Tylosin/Pyrantel Tartrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is removing those portions of the animal drug regulations which reflect approval of several new animal drug applications (NADA's), one held by The Eugene Ingmand Co. for the use of a tylosin Type A medicated article; two held by Kay Dee Feed Co., one for the use of a tylosin Type A medicated article, and another for the use of a tylosin-sulfamethazine Type A medicated article; and one held by Good-Life Division of Central Soya Co., Inc., for the use of a pyrantel tartrate Type A medicated article. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

**EFFECTIVE DATE:** August 6, 1990.

**FOR FURTHER INFORMATION CONTACT:** Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

**SUPPLEMENTARY INFORMATION:** In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of: The Eugene Ingmand Co.'s NADA 91-465 which provides for the use of a tylosin Type A medicated article to make a Type C medicated swine feed; Kay Dee Feed Co.'s NADA 111-814 which provides for

the use of a tylosin Type A medicated article to make a Type C chicken, swine, and beef cattle feed; Kay Dee Feed Co.'s NADA 128-255 which provides for the use of a tylosin-sulfamethazine Type A medicated article to make a Type C swine feed; and Good-Life Division of Central Soya Co., Inc.'s NADA 134-286 which provides for use of a pyrantel tartrate Type A medicated article to make a Type C swine feed. This document amends 21 CFR 558.485(a)(14), 558.625 (b)(49) and (b)(56), and 558.630(b)(8) to reflect the withdrawal of approval of these NADA's.

Also, since The Eugene Ingmand Co. and Kay Dee Feed Co. are no longer sponsors of any approved NADA's, 21 CFR 510.600 (c)(1) and (c)(2) are amended to remove the firms' entries from the list of sponsors of approved applications.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 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 parts 510 and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

##### § 510.600 [Amended]

2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entries "The Eugene Ingmand Co." and "Kay Dee Feed Co.", and in the table in paragraph (c)(2) by removing the entries "021533" and "026848", respectively.

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. 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).

**§ 558.485 [Amended]**

4. Section 558.485 Pyrantel tartrate is amended by removing and reserving paragraph (a)(14).

**§ 558.625 [Amended]**

5. Section 558.625 Tylosin is amended by removing and reserving paragraphs (b)(49) and (b)(56).

**§ 558.630 [Amended]**

6. Section 558.630 Tylosin and sulfamethazine is amended in paragraph (b)(8) by removing the number "026848".

Dated: July 12, 1990.

Gerald B. Guest,

Director, Center for Veterinary Medicine,

[FR Doc. 90-17314 Filed 7-24-90; 8:45 am]

BILLING CODE 4190-01-M

**21 CFR Part 175**

[Docket No. 87F-0327]

**Indirect Food Additives: Adhesives and Components of Coatings**

**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 ethylene-acrylic acid-carbon monoxide copolymer as an adhesive in multilayer structures intended for use in contact with food. This action is in response to a petition filed by The Dow Chemical Co.

**DATES:** Effective July 25, 1990; written objections and requests for a hearing by August 24, 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:** 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 October 29, 1987 (52 FR 41628), FDA announced that a food additive petition (FAP 7B4037) had been filed by The Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, proposing that § 175.105 Adhesives (21 CFR 175.105) be amended to provide for the safe use of ethylene-acrylic acid-carbon monoxide copolymer as an adhesive in multilayer structures intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The

agency concludes that these data establish the safe use of the food additive, ethylene-acrylic acid-carbon monoxide copolymer, and that § 175.105 (21 CFR 175.105) should be amended by alphabetically adding it as a new entry in the table in paragraph (c)(5).

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 August 24, 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 the 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 175**

Adhesives, 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, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

**PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS**

1. The authority citation for 21 CFR part 175 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 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry in the table to read as follows:

**§ 175.105 Adhesives.**

(c) \* \* \*

(5) \* \* \*

| Substances                                                                 | Limitations |
|----------------------------------------------------------------------------|-------------|
| Ethylene-acrylic acid-carbon monoxide copolymer (CAS Reg. No. 97756-27-9). |             |

Dated: July 12, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-17316 Filed 7-24-90; 8:45 am]

BILLING CODE 4190-01-M

**21 CFR Part 178**

[Docket No. 89F-0157]

**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 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer for polymers used as components of adhesives, gaskets, cements, repeat-use rubber articles, and paper in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

**DATES:** Effective July 25, 1990; written objections and requests for a hearing by August 24, 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:** 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 June 1, 1989 (54 FR 23540), FDA announced that a food additive petition (FAP 9B4144) had been filed by Ciba Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer for polymers used as adhesives, gaskets, cements, repeat-use rubber articles, and paper additives in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive 2-methyl-4,6-bis[(octylthio)methyl]phenol is safe, and that the regulations should be amended by alphabetically adding a new entry in the table in paragraph (b) of § 178.2010.

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 August 24, 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 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, 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 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

#### § 178.2010 Antioxidants and/or stabilizers for polymers.

(b) \* \* \*

| Substances                                                             | Limitations                                                                |
|------------------------------------------------------------------------|----------------------------------------------------------------------------|
| 2-methyl-4,6-bis-[(octylthio)methyl]phenol (CAS Reg. No. 110553-27-0). | For use only:<br>1. In adhesives complying with § 175.105 of this chapter. |

| Substances | Limitations                                                                                                                                                                                                                                                                                                                                          |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | 2. At levels not to exceed 0.25 percent by weight of can-end cements and side-seam cements complying with § 175.300(b)(3)(xxxi) and (xxxi) of this chapter.                                                                                                                                                                                          |
|            | 3. At levels not to exceed 1 percent by weight of pressure-sensitive adhesives complying with § 175.125 of this chapter, petroleum alicyclic hydrocarbon resins complying with § 176.170 of this chapter, resins and polymers complying with § 176.180 of this chapter, and closures with sealing gaskets complying with § 177.1210 of this chapter. |
|            | 4. At levels not to exceed 0.5 percent by weight of finished rubber products complying with § 177.2600 of this chapter.                                                                                                                                                                                                                              |

Dated: July 12, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-17317 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

#### 21 CFR Part 178

[Docket No. 88F-0442]

#### 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 *N*-methyl-*N*-(1-oxo-9-octadecenyl) glycine as a corrosion inhibitor for lubricants with incidental food contact. This action is in response to a petition filed by Ciba-Geigy Corp.

**DATES:** Effective July 25, 1990; written objections and requests for a hearing by August 24, 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 St. SW., Washington, DC 20204, 202-472-5690.