heading of this document. Any objection 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.

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 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: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding a new entry under the headings ''Lists of Substances'' and ''Limitations'' to read as follows:

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

* * * * *

(a) * * *

(5) * * *

List of Substances	Limitations
* * *	* *
Monoisopropanolamine (CAS Reg. No. 78–96–6).	For use as a dispersant for titanium dioxide suspensions at a level not to exceed 0.68 percent by weight of titanium dioxide. The finished paper and paperboard will be used in contact with all food types under conditions of use E through G described in table 2 of paragraph (c) of this section.
* * *	* *

* * * * *

Dated: May 7, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–12961 Filed 5–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F–0730]

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 change the density specifications for ethylene-maleic anhydride copolymers intended for use in contact with food. This action is in response to a petition filed by Keller and Heckman LLP.

DATES: The regulation is effective May 24, 1999; written objections and requests for a hearing by June 23, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 8, 1998 (63 FR 47503), FDA announced that a food additive petition (FAP 8B4623) had been filed by Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520), to change the the density specifications from ''0.92–0.94'' to ''0.92 or greater'' for ethylene-maleic anhydride copolymers intended for use in contact with food.

The September 8, 1998, filing notice for the petition stated that the action resulting from the petition qualified for a categorical exclusion under 21 CFR 25.32(i). Upon further review, the agency determined that such a categorical exclusion is not appropriate for this action because the additive is expected to be present in the finished food-contact article at a level greater than 5 percent by weight. Consequently, the agency considered the environmental effects of this action.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency has determined that the petitioner has adequately demonstrated that ethylene-maleic anhydride copolymers with a density specification of ''0.92 or greater'' in place of ''0.92–0.94'', conform to the identity and specifications under § 177.1520(c), item 6 for ethylene-maleic anhydride copolymers. Thus, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 177.1520 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact persons 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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before June 23, 1999, file with the Dockets Management Branch (address above) written objection 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 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 objection 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, 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1520 is amended in the table in paragraph (c) by revising item ''6.'' under the heading ''Density'' 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 the polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
	* *	* * *		
6. Ethylene-maleic anhydride copolymers described in paragraph (a)(6) of this section for use as the adhesive component in multilaminate structures, or as the sealant layer in flexible packaging, in contact with food at temperatures not exceeding 49 °C (120 °F)	0.92 or greater		1.36 pct at 50 °C.	2.28 pct at 25 °C

* * * * *

Dated: May 5, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–12962 Filed 5–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Selenium, Vitamin E Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a previously approved supplemental new animal drug application (NADA) held by Schering-Plough Animal Health Corp. and to remove certain information no longer required in the regulations. The approval concerns use of selenium, vitamin E injection.

EFFECTIVE DATE: May 24, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ 07083–1982, provided information to support prior approval of supplemental NADA 30–315 for selenium, vitamin E injection. The supplement for use of 2 percent benzyl alcohol instead of 1:10,000 thimerosal had been approved by letter of August 10, 1981. FDA reviewed the information and concurred that the change in ingredient was approved. FDA also reviewed the information requirements of the animal drug regulations and determined that specification of ingredients other than active ingredients is not needed. Therefore, 21 CFR 522.2100 is amended to remove statement of ingredients other than active ingredients.

List of Subjects in 21 CFR Part 522

Animal drugs.

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.2100 [Amended]

2. Section 522.2100 *Selenium, vitamin E injection* is amended in paragraph (a)(1) by removing '', 250 milligrams polyoxyethylated vegetable oil, and 2.0 percent benzyl alcohol, and water for injection''; in paragraph (b)(1) by removing '', 100 milligrams of polyoxyethylated vegetable oil, 1:10,000 thimerosal, and water for injection''; and in paragraphs (c)(1), (d)(1), and (e)(1) by removing '', 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q.s''.

Dated: May 11, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–12963 Filed 5–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–99–038]

RIN 2115–AA97

Safety Zone: Unity Electric Co. Fireworks Display, Shinnecock Bay, Hampton Bays, NY

AGENCY: Coast Guard, DOT.