§ 172.898 Bakers yeast glycan.

* * * * *

(d) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the act do not preclude such use:

Use	Limitations
(1) In salad dressings as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Not to exceed a concentration of 5 percent of the finished salad dressing.
(2) In frozen dessert analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	In an amount not to exceed good manufacturing practice.
(3) In sour cream analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(4) In cheese spread analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(5) In cheese-flavored and sour cream-flavored snack dips as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 6, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective, September 5, 1980.

(Secs. 201(s) and 409 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s) and 348).)

Dated: August 29, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–27169 Filed 9–4–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 172

[Docket No. 79F–0417]

Polysorbate 60; Food Additives Permitted for Direct Addition to Food for Human Consumption

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of polysorbate 60 as a surfactant and wetting agent for natural and artificial colors intended for use in food. This action is based on a petition filed by General Foods Corp.

DATES: Effective September 5, 1980; objections by October 6, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF–334), 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 December 7, 1979 (44 FR 70568), the FDA announced that a food additive petition (FAP 7A3310) had been filed by General Foods Corp., Technical Center, 250 North St., White Plains, NY 10625, proposing that the food additive regulations be amended to provide for the safe use of polysorbate 60 as a surfactant and wetting agent for natural and artificial colors intended for use in food.

Following the evaluation of data in the petition and other relevant material, FDA concludes that § 172.836 *Polysorbate 60* (21 CFR 172.836) should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s) and 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 172 is amended in § 172.836 by adding a new paragraph (c)(15) to read as follows:

§ 172.836 Polysorbate 60.

* * * * *

(c) * * *

(15) As a surfactant and wetting agent for natural and artificial colors in food as follows:

(i) In powdered soft drink mixes in an amount not to exceed 4.5 percent by weight of the mix.

(ii) In sugar-based gelatin dessert mixes in an amount not to exceed 0.5 percent by weight of the mix.

(iii) In artificially sweetened gelatin dessert mixes in an amount not to exceed 3.6 percent by weight of the mix.

(iv) In sugar-based pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(v) In artificially sweetened pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 6, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective September 5, 1980.

(Secs. 201(s) and 409 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s) and 348))

Dated: August 29, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27167 Filed 9-4-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Parts 177 and 178

[Docket No. 79F-0393]

Polyoxymethylene Homopolymer; Antioxidants and/or Stabilizers for Polymers; Indirect Food Additives

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of 612/6 nylon copolymer as a stabilizer with polyoxymethylene homopolymer to be used in articles intended for food-contact use. This action is based on a food additive petition filed by E. I. du Pont de Nemours & Co.

DATES: Effective September 5, 1980. Objections by October 6, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: A notice published in the **Federal Register** of November 30, 1979 (44 FR 69010) announced that a food additive petition (FAP 9B3453) had been filed by E. I. du Pont de Nemours & Co., Wilmington, DE 19897, proposing that § 177.2480 (21 CFR 177.2480) and § 178.2010 (21 CFR 178.2010) be amended to provide for the safe use of nylon 612/6 copolymer as a stabilizer with polyoxymethylene homopolymer to be used in articles intended for food-contact use.

FDA has evaluated data in the petition and other relevant material and finds that §§ 177.2480 and 178.2010 should be amended as set forth below to include the petitioned additive.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 177 and 178 are amended to read as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. In Part 177 § 177.2480 is amended by revising paragraph (b)(1), redesignating paragraph (b)(1)(iii) as (b)(1)(iv) and adding new paragraph (b)(1)(iii) to read as follows:

§ 177.2480 Polyoxymethylene homopolymer.

* * * * *

(b) * * *

(1) Stabilizers (total amount of stabilizers not to exceed 1.9 percent and amount of any one stabilizer not to exceed 0.5 percent, except that Nylon 66/610/6 terpolymer or Nylon 612/6 copolymer may be used up to 1.5 percent of homopolymer by weight).

* * * * *

(iii) Nylon 612/6 copolymer (CAS Reg. No. 51733-10-9), weight ratio 6/1.

(iv) Tetrakis [methylene (3,5 di-*tert*-butyl-4-hydroxy-hydrocinnamate)] methane.

* * * * *

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

2. In Part 178 § 178.2010(b) is amended by alphabetically inserting a new item in the list of substances, to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * *	
Nylon 612/6 copolymer. (CAS Reg. No. 51733-10-9), weight ratio 6/1.	For use only at levels not to exceed 1.5 percent by weight of polyoxymethylene homopolymer as provided in § 177.2480(b)(1).
* * * * *	

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 6, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective September 5, 1980.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

Dated: August 29, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27168 Filed 9-4-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 182

[Docket No. 80N-0363]

Substances Generally Recognized as Safe; Reorganization

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reorganizing a portion of 21 CFR Part 182 to facilitate the safety review of substances generally recognized as safe (GRAS). This action revises the heading of Subpart F to read "Dietary Supplements" and establishes new Subpart I, "Nutrients," which sets forth all regulations currently in Subpart F.

EFFECTIVE DATE: September 5, 1980.

FOR FURTHER INFORMATION CONTACT: Lynn A. Larsen, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive safety review of direct and indirect human food ingredients classified as GRAS or subject to a prior sanction. Included in this review is an evaluation of the GRAS status of nutrients currently listed in Subpart F of Part 182. To facilitate the review of these ingredients, FDA is reorganizing a portion of Part 182 to provide separate subparts for food substances used in dietary supplements

and for those used as nutrients in conventional foods.

When FDA determines, as a result of the safety evaluation, that a substance may be affirmed as GRAS, the agency publishes a proposal to affirm GRAS status in accordance with the provisions of § 170.35 (21 CFR 170.35). Such proposals include deletion of the substance from the GRAS list in Part 182 (21 CFR Part 182) and issuance of a new regulation affirming GRAS status in Part 184 or Part 186 (21 CFR Parts 184 and 186).

Substances used as nutrients or in dietary supplements are currently presented in a combined listing in Subpart F of Part 182 entitled "Nutrients and/or Dietary Supplements." Because there exists the possibility that a substance may be affirmed as GRAS when used as a nutrient in conventional food while not being affirmed as GRAS when used as an ingredient in a dietary supplement, the agency may be faced with issuing two separate regulations. One regulation would affirm the ingredient's GRAS status as a nutrient in conventional food in Part 184 while another regulation would issue maintaining the ingredient's current position as used in a special dietary supplement in Part 182. This situation would unduly complicate the GRAS affirmation procedure. Accordingly, FDA has concluded that the consequences of keeping the current heading of "Nutrients and/or Dietary Supplements" are unacceptable.

Therefore, FDA is reorganizing Part 182. Current Subpart F is retitled "Dietary Supplements," and new Subpart I is entitled "Nutrients." New Subpart I will be an exact duplicate of current Subpart F, but as substances are affirmed as GRAS in Part 184 for use as nutrients in conventional food, they will be deleted from this Subpart. The substance would continue to be listed for use in dietary supplements in Part 182, Subpart F, until it is evaluated for this specific use.

The effect of this reorganization is to facilitate the GRAS review of these substances used as nutrients in conventional foods without in any way affecting the current GRAS status of substances used in dietary supplements.

The changes being made are nonsubstantive, and for this reason notice and public comment procedures are not appropriate or necessary.

The agency has determined under 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) 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.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 182 of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. By revising the heading of Subpart F to read as follows:

Subpart F—Dietary Supplements

* * * * *

2. By adding new Subpart I to read as follows:

Subpart I—Nutrients

Sec.

Subpart I—Nutrients

§ 182.8013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8065 Linoleic acid.

(a) *Product.* Linoleic acid prepared from edible fats and oils and free from chickedema facto:

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8159 Biotin.

(a) *Product.* Biotin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8191 Calcium carbonate.

(a) *Product.* Calcium carbonate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8195 Calcium citrate

(a) *Product.* Calcium citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8201 Calcium glycerophosphate.

(a) *Product.* Calcium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8210 Calcium oxide.

(a) *Product.* Calcium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8212 Calcium pantothenate.

(a) *Product.* Calcium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when

used in accordance with good manufacturing practice.

§ 182.8223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8245 Carotene.

(a) *Product.* Carotene.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8260 Copper gluconate.

(a) *Product.* Copper gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe for use at a level not exceeding 0.005 percent in accordance with good manufacturing practice.

§ 182.8265 Cuprous iodide.

(a) *Product.* Cuprous iodide.

(b) *Tolerance.* 0.01 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt as a source of dietary iodine in accordance with good manufacturing practice.

§ 182.8301 Ferric phosphate.

(a) *Product.* Ferric phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8304 Ferric pyrophosphate.

(a) *Product.* Ferric pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8306 Ferric sodium pyrophosphate.

(a) *Product.* Ferric sodium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8308 Ferrous gluconate.

(a) *Product.* Ferrous gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8311 Ferrous lactate.

(a) *Product.* Ferrous lactate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8315 Ferrous sulfate.

(a) *Product.* Ferrous sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8370 Inositol.

(a) *Product.* Inositol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8375 Iron reduced.

(a) *Product.* Iron reduced.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8431 Magnesium oxide.

(a) *Product.* Magnesium oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8434 Magnesium phosphate.

(a) *Product.* Magnesium phosphate (di- and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8443 Magnesium sulfate.

(a) *Product.* Magnesium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8446 Manganese chloride.

(a) *Product.* Manganese chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8449 Manganese citrate.

(a) *Product.* Manganese citrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8452 Manganese gluconate.

(a) *Product.* Manganese gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8455 Manganese glycerophosphate.

(a) *Product.* Manganese glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8458 Manganese hypophosphite.

(a) *Product.* Manganese hypophosphite.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8461 Manganese sulfate.

(a) *Product.* Manganese sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8464 Manganous oxide.

(a) *Product.* Manganous oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8530 Niacin.

(a) *Product.* Niacin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8535 Niacinamide.

(a) *Product.* Niacinamide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8580 D-Pantothenyl alcohol.

(a) *Product.* D-Pantothenyl alcohol.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8622 Potassium chloride.

(a) *Product.* Potassium chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8628 Potassium glycerophosphate.

(a) *Product.* Potassium glycerophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when

used in accordance with good manufacturing practice.

§182.8676 Pyridoxine hydrochloride.

(a) *Product.* Pyridoxine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8695 Riboflavin.

(a) *Product.* Riboflavin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8697 Riboflavin-5-phosphate.

(a) *Product.* Riboflavin-5-phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8772 Sodium pantothenate.

(a) *Product.* Sodium pantothenate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8875 Thiamine hydrochloride.

(a) *Product.* Thiamine hydrochloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8878 Thiamine mononitrate.

(a) *Product.* Thiamine mononitrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8930 Vitamin A.

(a) *Product.* Vitamin A.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8933 Vitamin A acetate.

(a) *Product.* Vitamin A acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8936 Vitamin A palmitate.

(a) *Product.* Vitamin A palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8945 Vitamin B_{12}.

(a) *Product.* Vitamin B_{12}.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8950 Vitamin D_2.

(a) *Product.* Vitamin D_2.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8953 Vitamin D_3.

(a) *Product.* Vitamin D_3.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Effective date. This regulation becomes effective September 5, 1980.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this regulation have been carefully analyzed, and it has been determined that the regulation does not involve major economic consequences as defined by that order. A copy of the regulatory analysis-assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: August 29, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27171 Filed 9-4-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate and Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc., providing for safe and effective use of pyrantel tartrate and tylosin premixes in manufacturing a complete swine feed.

EFFECTIVE DATE: September 5, 1980.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Bureau of Veterinary Medicine (HFV-138), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed an NADA (110-047) providing for combining 48-gram-per-pound pyrantel tartrate and 40-gram-per-pound tylosin premixes in manufacturing complete swine feeds. The feeds are indicated as an aid in prevention of migration and establishment of roundworm infections, as an aid in prevention of establishment of nodular worm infections, and either for prevention or treatment and control of swine dysentery.

Approval of this NADA relies in part upon safety and effectiveness data contained in NADA's for Pfizer's pyrantel tartrate and Elanco's tylosin (NADA's 43-290 and 41-275, respectively). Use of those data to support this NADA has been authorized