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

by both firms. This approval does not change the dosage levels or indications for the drugs, but merely provides for combining them in complete swine feeds. Therefore, it poses no increased human risk from exposure to residues of the drugs. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977) approval of this NADA has been treated as would an approval of a category II supplemental and does not require reevaluation of the safety and effectiveness data in NADA's 43–290 and 41–275.

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 this application may be seen in the office of the Hearing Clerk (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.

The agency has determined pursuant to 21 CFR 25.24(d)(1) (proposed December 11, 1979, 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact 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. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended as follows:

1. In § 558.485 by adding new paragraphs (d)(2)(iii) and (e) (5) and (6) to read as follows:

§ 558.485 Pyrantel tartrate.

* * * * *

(d) * * *

(2) * * *

(iii) Not more than 0.106 percent (960 grams/ton) pyrantel tartrate with not more than 500 grams per ton tylosin when produced from individual supplements and as provided in paragraphs (e) (5) and (6) of this section.

* * * * *

(e) * * *

(5) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin, 40 to 100 grams, as tylosin phosphate.

(i) *Indications for use.* For prevention of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(ii) *Limitations.* Use 100 grams tylosin per ton for at least 3 weeks followed by 40 grams tylosin per ton until market weight; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(6) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin 40 to 100 grams, as tylosin phosphate.

(i) *Indications for use.* Treatment and control of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(ii) *Limitations.* Administer tylosin in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 grams per gallon in drinking water for 3 to 10 days, 40 to 100 grams tylosin per ton in feed for 2 to 6 weeks; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

2. In § 558.625 by adding new paragraph (f)(2)(v) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(v) Pyrantel tartrate in accordance with § 558.485.

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

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 28, 1980.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 80–27166 Filed 9–4–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 812

[Docket No. 76N–0327]

Investigational Device Exemptions; OMB Approval and Effective Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Office of Management and Budget has approved the recordkeeping and reporting requirements in the final regulations prescribing procedures for investigational device exemptions. FDA also is extending the effective date of the regulation for certain investigations and is correcting several provisions.

DATES: For investigations begun on or before July 16, 1980 that are to continue after January 19, 1981, FDA is extending to December 4, 1980, the effective date of the regulation. FDA is retaining the July 16, 1980 effective date for investigation begun after July 16, 1980. Comments on the corrections by December 4, 1980; corrections are effective September 5, 1980.

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

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Bureau of Medical Devices (HFK–403), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–8162.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) published final regulations prescribing procedures for investigational device exemptions (the IDE regulations) in the Federal Register of January 18, 1980 (45 FR 3732). The IDE regulations became effective on July 16, 1980.

OMB Approval

The preamble to the IDE regulations, as well as the effective date statement, declared that the recordkeeping and reporting requirements were submitted to the Office of Management and Budget (OMB) for approval in accordance with the Federal Reports Act of 1942, which requires OMB to review and approve records and reports used by Federal agencies in the collection of information from the public. The January 18, 1980 document also stated that the IDE regulations would become effective July 16, 1980, provided that OMB approval was received by that date and that FDA would publish a notice in the Federal Register concerning OMB's decision.

On June 24, 1980, OMB approved without change the recordkeeping and reporting requirements of the IDE regulations, under OMB number 57–R0151.

Effective Date of the IDE Regulations

There has been confusion about the effective date of the IDE regulations. FDA has received several inquiries from the public concerning whether the July 16, 1980 effective date was contingent upon FDA's receiving OMB approval,

and whether the July 16 effective date was operative before FDA published notice of this approval. Some have misunderstood the preamble and thought that the regulation was not to become effective until 6 months after July 16.

Because OMB approved the recordkeeping and reporting requirements before July 16, 1980, the IDE regulation became effective on that date. This effective date was not contingent on publication of notice of OMB's approval. Thus, FDA is retaining the July 16, 1980 effective date for investigations subject to the regulation begun after that date. FDA believes, however, that the confusion about the effective date of the regulation for investigations begun before July 16 justifies a change in the effective date for these investigations. For investigations begun on or before July 16, 1980 that are expected to continue after January 19, 1981, FDA is extending the effective date to December 4, 1980. Under § 812.2(b)(2) of the IDE regulations (21 CFR 812.2(b)(2)), investigations begun on or before July 16, 1980 that are planned to be completed by January 19, 1981 do not require an approved IDE.

To have an approved IDE by December 4, 1980, sponsors of ongoing clinical investigations are required to take the steps necessary to obtain any required approvals from institutional review boards (IRB's) or FDA before that date. The IDE regulations prescribe the circumstances in which these approvals are required.

Corrections in Regulation

1. Section 812.5(a) of the final rule requires that all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions be stated on the label of an investigational device. Inclusion of this information in the labeling, although not necessarily on the label, meets sufficiently the purposes of this requirement. Often this information would not fit on a device's label.

2. FDA is revising § 812.20(a)(3) to correct an inconsistency between this provision and § 812.30(a) with respect to when a sponsor may begin an investigation.

3. FDA is deleting as unnecessary § 812.30(b)(5) which allows FDA to disapprove or withdraw approval of an application if there is reason to believe that the device, as used in the investigation, is ineffective. This ground for disapproval or withdrawal was already covered by § 812.30(b)(4). For clarity, FDA is also splitting present § 812.30(b)(4) into two paragraphs, (b)(4) and (5).

4. FDA is revising § 812.140(b)(4)(v) so that the sponsor of a nonsignificant risk device investigation is required to maintain in the sponsor's records a statement of the extent to which FDA's good manufacturing practice (GMP) regulations in Part 820 (21 CFR Part 820) will be followed in manufacturing the device, but not "a copy of any quality assurance program that is followed with respect to the device." The latter phrase was inadvertently included in the final IDE regulations and imposes an unnecessary requirement. To evaluate manufacturing practices for nonsignificant risk devices, FDA wishes sponsors to maintain, routinely, only a statement of the extent to which the GMP regulations will be followed and not a copy of the quality assurance program, unless required specifically under § 812.140(b)(4)(vi).

5. Section 812.150(b)(5) now requires submission of progress reports to FDA and IRB's for both significant risk and nonsignificant risk device investigations. FDA did not intend for sponsors of nonsignificant risk device investigations, which are regulated principally by IRB's, to make progress reports to FDA.

Accordingly, FDA is correcting §§ 812.5(a), 812.20(a)(3), 812.30(b)(4) and (5), 812.140(b)(4)(v), and 812.150(b)(5), as described above. These changes make minor corrections in a major rule that became effective on July 16, 1980 (for investigations begun after that date) after a long rulemaking proceeding in which there were several opportunities for public comment and participation with respect to the provisions now being changed. Also, sponsors of investigations need to know the requirements with which they must comply. Therefore, the Commissioner determines that good cause exists to find that notice and public procedures are impracticable, unnecessary, and contrary to the public interest. For the same reasons, and because some of the changes relieve restrictions, the Commissioner finds good cause for not delaying the effective date of these changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042–1043 as amended, 1049–1051 as amended, 1055, 1056–1058 as amended, 67 Stat. 477 as amended, 90 Stat. 565–574 (21 U.S.C. 331, 351, 352, 360j, 371(a), 372, 374, 381)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 812 as follows:

1. In § 812.5, paragraph (a) is revised to read as follows:

§ 812.5 Labeling of investigational devices.

(a) *Contents.* An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with § 801.1), the quantity of contents, if appropriate, and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use." The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

* * * * *

2. In § 812.20, paragraph (a)(3) is revised to read as follows:

§ 812.20 Application.

(a) * * *

(3) If more than one IRB must approve an investigation, and these approvals occur after submission of an application to FDA, a sponsor shall submit a supplemental application under § 812.35(b) to FDA following each additional IRB approval. A sponsor shall not begin an investigation or part of an investigation until the IRB has approved it and until § 812.30(a) allows the investigation to begin.

* * * * *

3. In § 812.30, paragraph (b)(4) and (5) is revised to read as follows:

§ 812.30 FDA action on applications.

* * * * *

(b) * * *

(4) There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadquate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.

(5) It is otherwise unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of:

(i) The report of prior investigations or the investigational plan;

(ii) The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or

(iii) Monitoring and review of the investigation.

* * * * *

4. In § 812.140, paragraph (b)(4)(v) is revised to read as follows:

§ 812.140 Records.

* * * * *

(b) * * *

(4) * * *

(v) A statement of the extent to which the good manufacturing practice regulation in Part 820 will be followed in manufacturing the device; and

* * * * *

5. In § 812.150, paragraph (b)(5) is revised to read as follows:

§ 812.150 Reports.

* * * * *

(b) * * *

(5) *Progress reports.* At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, the sponsor shall also submit progress reports to FDA.

* * * * *

Effective date. Corrections to §§ 812.5(a), 812.20(a)(3), 812.30(b)(4) and (5), 812.140(b)(4)(v), and 812.150(b)(5) are effective September 5, 1980.

(Secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042–1043 as amended, 1049–1051 as amended, 1055, 1056–1058 as amended, 67 Stat. 477 as amended, 90 Stat. 565–574 (21 U.S.C. 331, 351, 352, 360j, 371(a), 372, 374, 381))

Dated: August 26, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-28069 Filed 9-4-80; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 515

Cuban Assets Control Regulations; Communications

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control is amending the Cuban Assets Control Regulations. The purpose of the amendment is to revise § 515.542, to provide a general license for transactions incident to satellite telecommunications between the United States and Cuba for purposes of transmission of news coverage. The amendment also indicates that specific licenses may be issued on a case-by-case basis for transactions incident to other communications activities, such as provision of telephone and telegraph services between the United States and Cuba. The need for the amendment is the growing media interest in transmissions by satellite from Cuba to the United States. The effect of the amendment is that United States media organizations will be permitted to use satellite channels for the transmission of television news and news programs from Cuba.

EFFECTIVE DATE: September 5, 1980.

FOR FURTHER INFORMATION CONTACT: Dennis M. O'Connell, Director, Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220, (202) 376–0395.

SUPPLEMENTARY INFORMATION: Since the Regulations involve a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rule making, opportunity for public participation and delay in effective date are inapplicable.

Prior to its amendment, § 535.542 contained a general license authorizing all transactions of common carriers incidental to the receipt or transmission of mail and telecommunications with Cuba.

Paragraph (a) of the amended section continues the general license for the receipt and transmission of mail.

Paragraph (b) contains the new general license authorizing transactions incident to the use of satellite communications for the transmission of television news and news progams originating in Cuba by United States news organizations.

Paragraph (c) provides that licensing of other transactions incident to communications between the United States and Cuba will be handled by specific license on a case-by-case basis. Such transactions were literally within the provisions of the general license contained in § 515.542 prior to amendment. However, actual Office of Foreign Assets Control practice has been to issue a specific license authorizing appropriate transactions to each of the small number of common carriers providing telephone and telegraph service between the United States and Cuba. Accordingly, new paragraph (c) simply reflects existing Office practice, under which the relevant carriers have been operating for some time. This revision of section 515.542 does not affect outstanding specific licenses already issued to such carriers with respect to the provision of such communications services between the United States and Cuba. However, the revision will clarify the fact that all transactions incident to communications other than those covered by the general license in paragraph (b) require a specific license from the Office.

31 CFR Part 515 is amended by revising section 515.542 to read as follows:

§ 515.542 Communications.

(a) All transactions of common carriers incident to the receipt or transmission of mail between the United States and Cuba are hereby authorized.

(b) All transactions incident to the use of satellite channels for the transmission of television news and news progams originating in Cuba by United States news organizations are hereby authorized.

(c) Specific licenses may be issued on a case-by-case basis for transactions incident to the receipt or transmission of communications between the United States and Cuba, other than communications covered by paragraph (b) of this section. Specific licenses are generally issued for such transactions as entry into traffic agreements to provide telephone and telegraph services, provision of services, and settlement of charges under traffic agreements.

Dated: August 24, 1980.

(Sec. 5, 40 Stat. 415, as amended, 50 U.S.C. App. 5; sec. 620(a), 75 Stat. 445, (22 U.S.C. 2370(a)); Prov. 3447, 27 FR 1085, 3 CFR, 1959–1963 Comp.; E. O. 9193, 7 FR 5205, 3 CFR, Comp. Supp., p. 1174; E. O. 9989, 13 FR 4891, 3 CFR, 1943–1948 Comp. p. 748)

Susan M. Swinehart,

Acting Director.

Approved:

Richard J. Davis,

Assistant Secretary.

[FR Doc. 80-27225 Filed 9-4-80; 8:45 am]

BILLING CODE 4810-25-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

41 CFR Ch. 18, Parts 1, 2, 3, 7, 12, and 16.

[Procurement Regulation Directive 80–3 (dated March 31, 1980)]

Procurement Regulations; Miscellaneous Amendments

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This document amends the NASA Procurement Regulation (41 CFR Ch. 18). It reflects amendments contained in Procurement Regulation Directive 80–3 concerning the following areas:

1. Prohibition Against Contracts with Organizations Which Provide Quasi-Military Armed Forces for Hire.
2. Late Bids, Modifications of Bids or Withdrawal of Bids Clause.
3. Publicizing Procurement Actions.
4. Small Purchases.