

d. Paragraph (h)(2) is removed and paragraph (h)(3) is redesignated as (h)(2).

e. Paragraph (i) is amended in the first sentence, by removing the word "net" where it precedes "sales."

f. Paragraph (j)(3) concerning the BE-13:

1. In subparagraph (j)(3)(i) for Form BE-13A, remove the section on Exemptions, Total and Partial, under subparagraph (i)(B) and insert the following:

Exclusions and Exemptions

(a) Residential real estate held exclusively for personal use and not for profitmaking purposes is not subject to the reporting requirements. A residence which is an owner's primary residence that is then leased by the owner while outside the United States but which the owner intends to reoccupy, is considered real estate held for personal use. Ownership of residential real estate by a corporation whose sole purpose is to hold the real estate and where the real estate is for the personal use of the individual owner(s) of the corporation, is considered real estate held for personal use.

(b) An existing U.S. affiliate is exempt from reporting the acquisition of either a U.S. business enterprise, or a business segment or operating unit of a U.S. business enterprise, that it then merges into its own operations, if the total cost of the acquisition was \$1,000,000 or less and does not involve the purchase of 200 acres or more of U.S. land. (If the acquisition involves the purchase of 200 acres or more of U.S. land, it must be reported regardless of the total cost of the acquisition.)

(c) An established or acquired U.S. business enterprise, as consolidated, is exempt if its total assets (not the foreign parent's or existing U.S. affiliate's share) at the time of acquisition or immediately after being established were \$1,000,000 or less and it does not own 200 acres or more of U.S. land. (If it owns 200 acres or more of U.S. land, it must report regardless of the value of total assets.)

If exempt under (b) or (c), the existing U.S. affiliate or the established or acquired U.S. business enterprise must, nevertheless, file an "Exemption Claim, BE-13A," to validate the exemption.

2. In subparagraph (j)(3)(ii) for Form BE-13B, the section entitled Total Exemption under subparagraph (ii)(C) is revised as follows:

Total Exemption—The foreign parent or existing U.S. affiliate is exempt from filing a BE-13B if a BE-13A is not required to be filed.

3. In subparagraph (j)(4) concerning Form BE-14: Under Total Exemptions, paragraph (a) is revised as follows:

(a) Residential real estate held exclusively for personal use and not for profitmaking purposes is not subject to the reporting

requirements. A residence which is an owner's primary residence that is then leased by the owner while outside the United States but which the owner intends to reoccupy, is considered real estate held for personal use. Ownership of residential real estate by a corporation whose sole purpose is to hold the real estate and where the real estate is for the personal use of the individual owner(s) of the corporation, is considered real estate for personal use.

And in the paragraph (b), which follows, amend the \$500,000.00 to read \$1,000,000.

[FR Doc. 81-12441 Filed 4-23-81; 8:45 am]

BILLING CODE 3510-06-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 80F-0034]

Indirect Food Additives; Polymers Toluene

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 toluene as an adjuvant in the manufacture of polycarbonate resins, as requested in a petition filed by Mitsubishi Gas Chemical Co., Inc.

DATES: Effective April 24, 1981; objections by May 26, 1981.

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

FOR FURTHER INFORMATION CONTACT: Neal D. Singletary, Bureau of Foods (HFF-334), Food and Drug

Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 11, 1980 (45 FR 15673), FDA announced that a food additive petition (FAP 8B3403) had been filed by Mitsubishi Gas Chemical Co., Inc., c/o Springborn Institute for Bioresearch, Inc., Spencerville, OH 45887, proposing that § 177.1580 Polycarbonate resins (21 CFR 177.1580) be amended to provide for the safe use of toluene as an adjuvant in the manufacture of polycarbonate resins.

The Commissioner of Food and Drugs has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Commissioner's finding of no significant impact and the evidence supporting this finding, contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979; 44 FR 71742) may be seen in the Dockets Management Branch, Food and Drug Administration.

Having evaluated data in the petition and other relevant material, FDA concludes that the food additive regulations should be amended to provide for the safe use of toluene with the limitations set forth below.

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), Part 177 is amended in § 177.1580(b) by inserting alphabetically a new item in the list of substances to read as follows:

§ 177.1580 Polycarbonate resins.

• • • • •
(b) • • •

List of substances	Limitations
Toluene: (CAS Reg. No. 0001-08-883)	Not to exceed 800 parts per million as residual solvent in finished resin.

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 26, 1981 submit to the Dockets Management Branch (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 docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective April 24, 1981.

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

Dated: April 17, 1981.

William F. Randolph,

Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 81-12130 Filed 4-23-81; 8:45 am]

BILLING CODE 4110-03-M

ENVIRONMENTAL PROTECTION AGENCY

21 CFR Part 193

[FAP 9H5230/R70; PH FRL 1805-8]

Oxyfluorfen; Tolerances for Pesticides in Food Administered by the Environmental Protection Agency

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a regulation for residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] and its metabolites containing the diphenyl ether linkage in refined soybean oil at 0.25 part per million (ppm). This regulation was requested by Rohm & Haas Co., Inc. This regulation will establish the maximum permissible level for oxyfluorfen in refined soybean oil.

EFFECTIVE DATE: Effective on April 24, 1981.

ADDRESS: Written objections may be submitted to the: Hearing Clerk, Environmental Protection Agency, Rm. M-3708 (A-110), 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Richard F. Mountfort, Product Manager (PM) 23, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 412D, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703-557-7070).

SUPPLEMENTARY INFORMATION: EPA issued a notice that published in the

Federal Register of September 3, 1980 (45 FR 58495), that Rohm & Haas Co., Independence Mall West, Philadelphia, PA 19105, had filed a food additive petition (FAP 9H5230) with the EPA. This petition proposed the establishment of a food additive regulation permitting residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] and its metabolites containing the diphenyl ether linkage in refined soybean oil at 0.25 part per million (ppm) resulting from application to the growing crop. No comments or request for referral to an advisory committee were received in response to this notice of proposed rulemaking.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data included a rat oral LD₅₀ with an LD₅₀ greater than 5.0 grams (g)/Kilogram(kg), a rat cytogenetic study (negative); host mediated assay (negative); Ames test (negative); rat teratology study with no terata at 1,000 mg/kg of bw (highest dose) and a no-observed-effect level (NOEL) of 100 mg/kg of (bw), a three-generation rat reproduction study with a NOEL of 10 ppm; 26-week progress report of a 2-year dog feeding study; a 90-day rat feeding study with a NOEL of 1,000 ppm; a 24-month rat feeding study (chronic toxicity/oncogenicity) with a NOEL of 40 ppm; and a 20-month mouse feeding study (chronic toxicity/oncogenicity) with a NOEL of 2 ppm.

Based on the mouse chronic feeding study with a NOEL of 2 ppm and a 100-fold safety factor the acceptable daily intake (ADI) for humans is 0.003 mg/kg of bw/day. The maximum permissible intake (MPI) is 0.1800 mg/day for a 60 kg person. A concurrent regulation (PP8F2058/R301) for tolerances in corn grain and soybeans (40 CFR 180.381) appears elsewhere in this issue of the Federal Register. The tolerances have a theoretical maximal residue contribution (TMRC) of 0.0367 mg/day in a 1.5 kg diet, or 20.37 percent of the MPI.

To reinforce the present findings, the petitioner submitted a complete draft report on the 2-year dog feeding study prior to September 22, 1980 and has agreed to conduct a second teratology study with a nonrodent species.

The nature of the residue of the pesticide is adequately delineated, and an adequate analytical method (a gas chromatographic procedure using an electron capture detector) is available for enforcement purposes.

One of the solvents used in the production of technical oxyfluorfen, perchloroethylene <0.1 percent, has been shown to produce liver tumors in mice. The agency is presently

assembling available information pertaining to perchloroethylene, which has wide usage outside of pesticide applications. The review will assess the health significance of perchloroethylene and is not complete at this time. The evidence on tumor production, however, does initiate a presumption against registration pursuant to 40 CFR 162.11(a)(3)(ii) for the proposed uses of oxyfluorfen. After intensive review, the agency has made a preliminary finding that potential benefits associated with the use of oxyfluorfen outweigh risks from perchloroethylene. The benefits of oxyfluorfen will be discussed in a document to be available at a later date.

An applicator risk analysis was performed to determine the risk associated with perchloroethylene resulting from applications of oxyfluorfen for all uses proposed. The maximum worst-case risk of tumor development from exposure to perchloroethylene via these uses is calculated to be four (4) incidents of tumor development in 100,000 applicators. The actual risk may be lower than this theoretical calculation since the actual levels of perchloroethylene in air may be lower than the theoretical estimates due to air movement or other climatic factors.

In addition to the applicator risk study, analyses were performed on the raw commodity soybean samples to detect residues of perchloroethylene. No residues were detected at the limit of sensitivity for the method (0.05 ppm). Due to the volatile nature of perchloroethylene and the nature of the proposed use patterns for oxyfluorfen (i.e., preemergence or post emergence directed sprays), residues of perchloroethylene in these commodities may be lower than 0.05 ppm.

The agency has calculated a risk through ingestion using 0.05 ppm (method sensitivity) as a base. For soybeans, the maximum risk through ingestion is calculated to be five (5) incidents in 100,000,000.

The petitioner produces technical oxyfluorfen containing less than 200 ppm perchloroethylene. Based on the toxicology testing (all tested oxyfluorfen involved included perchloroethylene at less than 0.1 percent), the small risk cited above, and benefit analyses discussed in the position document, the agency has made a preliminary conclusion that the proposed registration of oxyfluorfen containing less than 200 ppm of perchloroethylene will not cause an unreasonable adverse effect on the environment.

The pesticide is considered useful for the purpose for which the regulation is

sought, and it is tentatively concluded that the regulation for oxyfluorfen residues in refined soybean oil at 0.25 ppm established by amending 21 CFR 193.325 will protect the public health. Therefore, the regulation is established as set forth below.

Any person adversely affected by this regulation may, on or before May 28, 1981, file written objections with the Hearing Clerk, EPA, Rm. M-3708 (A-110), 401 M St., SW., Washington, D.C. 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted, if the objections are legally sufficient to justify the relief sought.

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because it will not have an annual effect on the economy of \$100 million or more; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In general, tolerance regulations have beneficial impacts on affected industries and the public.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the Document Control Office, EPA, Rm. 107, 401 M St., SW., Washington, D.C. 20460. Effective date: April 24, 1981.

For information on Regulatory Flexibility Act requirements, see Appendix to this rule.

(Sec. 409(c), 72 Stat. 1786, (21 U.S.C. 348(c)(1)))

Dated: March 24, 1981.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

Therefore, Subpart A of 21 CFR Part 193 is amended by adding paragraph (d) under § 193.325 to read as follows:

§ 193.325 Oxyfluorfen.

• • • • •

(d) Tolerances are established for the combined residues of the herbicide oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4- (trifluoromethyl) benzene] and its metabolites containing the diphenyl ether linkage in refined soybean oil at 0.25 part per million, when present therein as a result of its application to the growing crop.

Appendix

Certification Under Regulatory Flexibility Act

Congress recently enacted the Regulatory Flexibility Act (Pub. L. 96-543, 94 Stat. 1164, 5 U.S.C. 601-612, effective January 1, 1981). The purpose of the Act is to assure that the Agency analyzes the effect of regulatory requirements on small businesses, Government jurisdictions, and organizations (collectively referred to as "small entities"). The law requires that all "notice-and-comment" rulemaking, both proposed and final, be accompanied by an initial or final regulatory flexibility analysis, or by a certification by the Administrator that no such analysis is necessary because the regulation will not have a significant adverse impact on a substantial number of small entities.

Under Sec. 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 346a), the Agency is authorized to establish by regulation tolerance levels, or exemptions from the requirements for a tolerance, for pesticides resulting in residues on raw agricultural commodities. Under Sec. 409 of the same Act (21 U.S.C. 348), the Agency is authorized to issue regulations establishing permissible levels of residues of pesticides found as additives in processed food or feed. These tolerance and additive regulations are intended to protect the public while giving appropriate consideration to the production of an adequate, wholesome and economical food supply.

The establishment of a tolerance or an exemption or an additive level allows a pesticide product to be registered for a particular use resulting in residues on food or feed. This generally has beneficial economic impacts on the producer, distributor, and professional applicator of the pesticide, all of whom benefit through sale of the pesticide. It also benefits the ultimate user of the pesticide, usually a grower or food processor, who would otherwise not be able to sell crops containing residues of that pesticide.

The proposed regulation would establish a food additive regulation for oxyfluorfen in refined soybean oil at 21 CFR Part 193. This regulation supports a proposed use pattern for oxyfluorfen in soybeans and will permit registration to include that use. There is no potential for adverse impact.

Accordingly, I hereby certify that this proposed regulation would not, if promulgated, have a significant adverse impact on a substantial number of small entities. Therefore, this regulation does not require a regulatory flexibility analysis.

Dated: February 27, 1981.

Walter C. Barber, Jr.,
Acting Administrator.

[FR Doc. 81-12406 Filed 4-23-81; 8:45 am]

BILLING CODE 6560-32-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect the change of sponsor name for a new animal drug application (NADA) from Heinold Elevator Co., Inc., to Heinold Feeds, Inc., and to revise the list of sponsors of approved NADA's to reflect this change.

EFFECTIVE DATE: April 24, 1981.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Heinold Elevator Co., Inc., Kouts, IN 46347, has advised that it has changed the firm name to Heinold Feeds, Inc. The Bureau of Veterinary Medicine is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This action, the change of sponsor of an NADA, does not involve changes in manufacturing facilities, equipment, procedures, or personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), approval of this action does not require reevaluation of the safety and effectiveness data in the parent application.

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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

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), § 510.600 is amended in paragraph (c)(1) by removing the entry for "Heinold Elevator Co., Inc.," and by adding a new sponsor entry alphabetically for "Heinold Feeds, Inc.," and in paragraph (c)(2) in the entry for "043727" by removing the sponsor name "Heinold Elevator Co., Inc.," and inserting in its place the name "Heinold Feeds, Inc." to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

Firm name and address		Drug labeler code
Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347..		043727
Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347.		043727

Effective date, April 24, 1981.

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

Dated: April 16, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

(FR Doc. 81-12918 Filed 4-23-81; 8:45 am)

BILLING CODE 4110-03-M

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Oral Dosage Form New Animal Drugs Not Subject to Certification; Diethylcarbamazine Citrate Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) announces that the animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by EVSCO Pharmaceutical Corp. providing for safe and effective use of 100 and 300 milligram (mg) diethylcarbamazine citrate tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

EFFECTIVE DATE: April 24, 1981.

FOR FURTHER INFORMATION CONTACT:

Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: EVSCO Pharmaceutical Corp., P.O. Box 209, Harding Highway, Buena, NJ 08310, filed a supplemental NADA (100-690) providing for use of 100 and 300 mg diethylcarbamazine citrate tablets in dogs for prevention of heartworm disease caused by *Dirofilaria immitis* and in dogs and cats as an aid in the treatment of ascarid infections caused by *Toxocara canis* and *Toxascaris leonina*. EVSCO currently holds approval for use of 50, 200, and 400 mg tablets. This supplement adds the 100 and 300 mg sizes. Approval of this supplement does not change the approved condition of use of the drug. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in the original application. The supplemental NADA is approved, and the regulations are amended to reflect the approval. In addition, the regulation (21 CFR 520.622a) is editorially revised to reflect current format.

The agency has determined pursuant to 21 CFR 25.24(d)(1)(ii) (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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

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 520 is amended by revising § 520.622a to read as follows:

§ 520.622a Diethylcarbamazine citrate tablets.

(a) *Sponsors.* (1) See 000010 and 010042 in § 510.600(c) of this chapter for use of 50, 200, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(2) See 000003 in § 510.600(c) of this chapter for use of 100, 200, and 300 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs.

(3) See 012518 in § 510.600(c) of this chapter for use of 50, 200, or 400 milligram tablets for prevention of heartworm disease in dogs, as an aid in the control of ascarid infections in dogs, and as an aid in the treatment of ascarid infections in dogs and cats.

(4) See 017030 in § 510.600(c) of this chapter for use of 50, 100, 200, 300, and 400 milligram tablets for prevention of heartworm disease in dogs and as an aid in the treatment of ascarid infections in dogs and cats.

(b) *Conditions of use—(1) Dosage/indications for use.* (i) Three milligrams per pound of body weight daily for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

(2) *Limitations.* Administer orally either pulverized and given in feed or water or directly by mouth. For the treatment of ascarid infections, repeat in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions because of pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date, April 24, 1981.

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

Dated: April 20, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

(FR Doc. 81-12325 Filed 4-23-81; 8:45 am)

BILLING CODE 4110-03-M

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Oral Dosage Form New Animal Drugs Not Subject to Certification; Primidone Tablets**AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Bolar Pharmaceutical Co., Inc., providing for use of 50-milligram primidone tablet in addition to the existing approved 250-milligram tablet as an anti-convulsant in dogs.

EFFECTIVE DATE: April 24, 1981.**FOR FURTHER INFORMATION CONTACT:**

Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, NY 11726, filed a supplemental NADA (107-397) providing for use of a 50-milligram primidone tablet in addition to the existing approved 250-milligram tablet as an anti-convulsant for treatment of dogs for idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease. The product is for oral administration by or on the order of a licensed veterinarian. This action, providing solely for an additional strength tablet, does not affect the currently approved use (see 21 CFR 520.1900). Therefore, in accordance with the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), approval of this supplement does not require reevaluation of the safety and effectiveness data in the parent application. The supplemental NADA is approved, and the regulations amended to reflect the approval.

Approval of this supplement did not require generation of new safety and effectiveness data. Therefore, a freedom of information summary described in 21 CFR 514.11(e)(2) is not required.

The agency has determined pursuant to 21 CFR 25.24(d)(1)(i) (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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is

therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

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 520 is amended in § 520.1900 by revising paragraph (b) to read as follows:

§ 520.1900 Primidone tablet.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter for use of 250 milligram tablets; see 000046 and 000725 for use of 50 and 250 milligram tablets.

Effective date. April 24, 1981.

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

Dated: April 20, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

(FR Doc. 81-12326 Filed 4-23-81; 8:45 am)

BILLING CODE 4110-03-M

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Oral Dosage Form New Animal Drugs Not Subject to Certification; Trimethoprim and Sulfadiazine Tablets**AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Burroughs Wellcome Co. providing for safe and effective use of a combination antibacterial drug for treating large dogs.

EFFECTIVE DATE: April 24, 1981.**FOR FURTHER INFORMATION CONTACT:**

Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION:

Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, filed a supplemental NADA (95-614) providing for a 960-milligram (mg) size of the combination proprietary drug product Tribriksen Tablet (160 mg of trimethoprim and 800 mg of sulfadiazine) to facilitate safe treatment of large dogs. The firm also holds approval under the same NADA for the same product in smaller-sized tablets. The drug is indicated where control of

bacterial infection is required during treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

This approval does not change the approved use of the drug. Consequently, approval of this application does not require reevaluation of the safety and effectiveness under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367, December 23, 1977).

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 Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-82, 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)(i) (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.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

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 520 is amended in § 520.2610 by revising paragraphs (a) and (b) to read as follows:

§ 520.2610 Trimethoprim and sulfadiazine tablets.

(a) *Specifications.* Each tablet contains 30 milligrams (5 milligrams of trimethoprim and 25 milligrams of sulfadiazine), 120 milligrams (20 milligrams of trimethoprim and 100 milligrams of sulfadiazine), 480 milligrams (80 milligrams of trimethoprim and 400 milligrams of sulfadiazine) or 960 milligrams (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine).

(b) *Sponsor*. See No. 000081 in § 510.600(c) of this chapter for 30, 120, 480, and 960 milligram tablets. See No. 013947 in § 510.600(c) of this chapter for 120 and 480 milligram tablets.

Effective date: April 24, 1981.

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

Dated: April 20, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 81-12327 Filed 4-23-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 522

Animal Drugs, Feeds, and Related Products; Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Euthanasia Solutions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) sponsored by Burns-Biotec Laboratories, Inc., providing for use of a euthanasia solution for humane, painless, and rapid euthanasia of dogs.

EFFECTIVE DATE: April 24, 1981.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Burns-Biotec Laboratories, Inc., 8530-8536 K St., P.O. Box 3113, Omaha, NE 68103 filed an NADA (119-807) providing for use of an injectable euthanasia solution containing 390 milligrams (mg) of pentobarbital sodium and 50 mg of phenytoin sodium per milliliter (mL) for intravenous or intracardiac administration for humane, painless, and rapid euthanasia of dogs. The application is approved, and the regulations are amended to reflect the approval.

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 Dockets Management Branch (formerly the Hearing Clerk's office) (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 Director, Bureau of Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Director's finding of no significant impact and the evidence supporting this finding, contained in a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(ii)(a) and (e)(2) and (g) may be seen in the Dockets Management Branch, Food and Drug Administration.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))), 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 522 is amended by revising § 522.900 to read as follows:

§ 522.900 Euthanasia solution.

(a)(1) *Specifications*. Each milliliter contains 200 milligrams of N-[2-(m-methoxy-phenyl)-2-ethyl-butyl-(1)]-gamma-hydroxybutyramide, 50 milligrams of 4, 4'-methylene-bis(cyclohexyl-trimethyl-ammonium iodide), 5 milligrams of tetracaine hydrochloride, with 0.6 milliliter dimethylformamide in distilled water.

(2) *Sponsor*. No. 000039 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is used for the humane euthanasia of animals without excitation or pain. It is used in dogs, cats, horses, mink, small laboratory animals (mice, rats, guinea pigs, and rabbits) and birds (pigeons and parakeets).

(ii) *Dosage*—(a) *Dogs*. Intravenous or intracardiac injection: Use 0.3 milliliter/kilogram (0.14 milliliter/pound). Intrapulmonary injection: For animals weighing up to 10 kilograms, use 7 to 10 milliliters. In larger animals, follow initial 10 milliliters by another 3 to 10 milliliters by intrapulmonary or intracardiac administration.

(b) *Cats*. Intravenous injection: Use 0.3 milliliter/kilogram (0.14 milliliter/pound). Intrapulmonary injection: Kittens a few days old, 1 milliliter; kittens up to 6 months of age, 3 milliliters; cats over 6 months of age, 5 milliliters; cats weighing more than 5 kilograms (11 pounds), 10 milliliters.

(c) *Horses*. Intravenous injection: Use 4 to 6 milliliters/50 kilograms (110 pounds of body weight).

(d) *Mink*. Intraperitoneal injection: 0.5 to 1 milliliter.

(e) *Birds and small laboratory animals*. Intrapulmonary injection: 0.5 to 2 milliliters.

(iii) Not to be used for therapeutic purposes.

(iv) Do not use in animals intended for food.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications*. Each milliliter of nonsterile solution contains 390 milligrams of pentobarbital sodium and 50 milligrams of phenytoin sodium.

(2) *Sponsor*. No. 000845 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Indications for use*. For the humane, painless, and rapid euthanasia of dogs.

(ii) *Amount*. One milliliter (390 milligrams of pentobarbital sodium and 50 milligrams of phenytoin sodium) for each 10 pounds of body weight.

(iii) *Limitations*. For intravenous injection or intracardiac injection when intravenous use is impractical. Do not use for therapeutic purposes. Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: April 24, 1981.

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

Dated: April 20, 1981.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 81-12329 Filed 4-23-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 558

Animal Drugs, Feeds, and Related Products; New Animal Drugs for Use in Animal Feeds; Oxytetracycline

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations to reflect certain new animal drug applications (NADA's) sponsored by Ralston Purina Co. which provide for use of oxytetracycline in animal feed.

EFFECTIVE DATE: April 24, 1981.

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: Ralston Purina Co., Checkerboard Square, St. Louis, MO 63199 (Ralston), is the sponsor of NADA's 94-959 and 94-960.