appropriate regulations when initially introduced into interstate commerce on or after January 1, 2000. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32884 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Fomepizole

AGENCY: Food and Drug Administration, HHS.

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) filed by Orphan Medical, Inc. The NADA provides for intravenous use of fomepizole solution as an antidote for ethylene glycol poisoning in dogs.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305, is sponsor of NADA 141–075, which provides for the use of Antizol-Vet™ (sterile injectable fomepizole solution) for use as an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol. The drug is for veterinary prescription use only. The NADA is approved as of November 25, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding a new § 522.1004 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Orphan Medical, Inc., has not previously been added to the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)). At this time, § 510.600(c)(1) and (c)(2) are amended to include entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 25, 1996, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

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

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Orphan Medical, Inc.,'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''062161'' to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305	062161
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
*	*
*	*
*	*
*	
062161	Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305.
*	*
*	*
*	*
*	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

4. New § 522.1004 is added to read as follows:

§ 522.1004 Fomepizole.

(a) *Specifications.* Two vials, one containing 1.5 grams fomepizole (1.5 milliliter of 1.0 gram fomepizole per milliliter sterile aqueous solution), and one vial containing 30 milliliters of 0.9 percent sodium chloride injection USP (as a diluent).

(b) *Sponsor.* See 062161 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 20 milligrams per kilogram initially, 15 milligrams per kilogram at 12 and 24 hours, and 5 milligrams per kilogram at 36 hours.

(2) *Indications for use.* As an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol.

(3) *Limitations.* Administer intravenously. For use by or on the order of a licensed veterinarian.

Dated: December 16, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32883 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Tilmicosin Phosphate Type A Medicated Article

AGENCY: Food and Drug Administration, HHS.

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) filed by Elanco Animal Health. The NADA provides for the use of a Type A medicated article containing tilmicosin phosphate in manufacturing a Type B or Type C medicated feed indicated for the control of swine respiratory disease associated with certain bacterial organisms.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–064, which provides for the use of a Type A medicated article containing 90.7 grams (g) of tilmicosin (as tilmicosin phosphate) per pound in manufacturing a Type C medicated feed (181.8 g to 363.6 g of tilmicosin per ton) indicated for the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*. The NADA is approved as of December 27, 1996, and the regulations are amended by adding new § 558.618 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the agency is amending 21 CFR 556.735 to establish a tolerance for residues of tilmicosin in edible swine tissues. As discussed in the freedom of information summary, parent tilmicosin was selected as the marker residue, and liver as the target tissue, for determination of tilmicosin residues in edible swine tissues.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity for the use of tilmicosin in swine beginning December 27, 1996, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

A high performance liquid chromatographic method is available to determine the presence and amount of the marker residue in swine liver. In addition, a high performance liquid chromatographic/mass spectrometric method is available to confirm the presence of the marker residue in liver. Both methods have been validated by FDA and the U.S. Department of Agriculture and are for regulatory purposes. The methods are available for public inspection at the Dockets Management Branch (address above) and are attached to the freedom of information summary for this NADA. Requests for copies of these methods should be made under the Freedom of Information Act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Tilmicosin phosphate is a new animal drug used in a Type A medicated article to make Type B or Type C medicated feeds. Tilmicosin phosphate is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). Therefore, as provided in 21 CFR 558.4(b), an approved Form FDA 1900 is required for making a Type B or Type C medicated feed containing tilmicosin phosphate as in the approved subject NADA and in newly added § 558.618. Under section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (ADAA), Pub. L. 104–250, medicated feed applications have been replaced by feed mill licensing.

Tilmicosin phosphate is limited to use under the professional supervision of a licensed veterinarian. It is the first veterinary feed directive (VFD) drug to be approved since the enactment of the ADAA. Pending issuance of regulations to implement veterinary feed directives, Congress directed FDA to set forth in the new animal drug approval notice required by section 512(i) of the act any necessary conditions relating to the