(2) * * *

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

labeling, advertising, distribution, holding, and use of a VFD drug. Accordingly, this regulation sets forth necessary conditions for tilmicosin phosphate (NADA 141–064) including the information that shall be included in a VFD:

- The name, address, and phone number of the veterinarian and the client;
- Identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals;
- Date of treatment and, if different, date of prescribing the VFD drug;
- The condition or disease being diagnosed or treated;
- Name of the animal drug;
- Level of animal drug in the feed and the amount of feed;
- Feeding instructions with withdrawal time;
- Any special instructions and cautionary statements necessary for use of the drug in conformance with the approval;
- Expiration date of the VFD;
- Number of refills, if permitted by the approval;
- Signature of the veterinarian; and
- The veterinarian's license number and name of the State issuing the license.

At such time as FDA finalizes general regulations governing VFD drugs, the general regulations may supersede certain specific VFD requirements of this approval regulation.

List of Subjects

*21 CFR Part 556*

Animal drugs, Foods.

*21 CFR Part 558*

Animal drugs, Animal feeds.

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 556 and 558 are amended as follows:

## PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

2. Section 556.735 is revised to read as follows:

### § 556.735 Tilmicosin.

A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) of cattle at 1.2 parts per million (ppm) and of swine at 7.2 ppm.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

4. Section 558.4 is amended in paragraph (d) in the ''Category II'' table by alphabetically adding a new entry for ''Tilmicosin'' to read as follows:

### § 558.4 Medicated feed applications.

* * * * *

(d) * * *

CATEGORY II

| Drug | Assay limits percent[1] Type A | Type B maximum (100x) | Assay limits percent[1] Type B/C[2] |
|---|---|---|---|
| * | * * | * | * |
| Tilmicosin | 90—110 | 18.2 g/lb (4.0 %). | 85—115 |

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

5. New § 558.618 is added to read as follows:

### § 558.618 Tilmicosin.

(a) *Approvals.* Type A medicated articles: 90.7 grams of tilmicosin (as tilmicosin phosphate) per pound (200 grams per kilogram) to 000986 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in any feed containing bentonite.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use.* It is used in swine feed as follows:

(1) *Amount per ton.* 181.8 grams to 363.6 grams tilmicosin.

(2) *Indications for use.* For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

(3) *Limitations.* For use in swine feed only. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Withdraw 7 days before slaughter. Federal law restricts this drug to use under the professional supervision of a licensed veterinarian. Any animal feed bearing or containing this drug shall be fed to animals only by or upon a lawful veterinary feed directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice. VFD's for tilmicosin phosphate shall not be refilled.

(4) *VFD Requirements.* This drug and any article or feed manufactured from it shall bear the following cautionary statements: ''Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.'' A VFD shall contain the following information: The name, address, and phone number of the veterinarian and the client; identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals; date of treatment and, if different, date of prescribing the VFD drug; the condition or disease being diagnosed or treated; name of the animal drug; level of animal drug in feed and amount of feed; feeding instructions with withdrawal time; any special instructions and cautionary statements necessary for use of the drug in conformance with the approval; expiration date of VFD; number of refills, if permitted by approval; signature of the veterinarian; veterinarian's license number and name of the State issuing the license.

Dated: December 17,1996.

Stephen F. Sundlof,

*Director, Center for Veterinary Medicine.*

[FR Doc. 96–32881 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF STATE

## 22 CFR Part 171

**[Public Notice 2492]**

## Privacy Act of 1974; Implementation

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending its regulations by exempting portions of a record system from certain provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a). Certain portions of the Garnishment of Wages