(3) A statement that a solution containing an additive drug should not be stored.

(d) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

§ 310.510 [Removed]

14. Section 310.510 *Use of aerosol drug products containing zirconium* is removed.

§ 310.513 [Removed]

15. Section 310.513 *Chloroform, use as an ingredient (active or inactive) in drug products* is removed.

§ 310.525 [Removed]

16. Section 310.525 *Sweet spirits of nitre drug products* is removed.

§ 310.526 [Removed]

17. Section 310.526 *Camphorated oil drug products* is removed.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6411 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Tablet

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 supplemental new animal drug application (NADA) filed by Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for oral administration of lufenuron tablets at a minimum dose of 30 milligrams per kilogram (mg/kg) for the control of flea populations on cats.

EFFECTIVE DATE: March 14, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish P1., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, filed supplemental NADA 141–035, which provides for oral administration of Program® (lufenuron) tablets to cats 6 weeks of age or older. The drug is approved in 90- or 204.9-mg tablets, given once a month, directly or broken and mixed into wet food, for the control of flea populations. Lufenuron has no deleterious effect on adult fleas but it prevents most flea eggs from hatching or maturing into adults. The supplemental NADA is approved as of January 23, 1997, and the regulations are amended in 21 CFR 520.1288 by revising the heading for paragraph (c) and by adding new paragraph (d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning January 23, 1997, because the application contains substantial evidence of effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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.

List of Subjects in 21 CFR Part 520

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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1288 is amended by revising the heading for paragraph (c) and by adding new paragraph (d) to read as follows:

§ 520.1288 Lufenuron tablets.

* * * * *

(c) *Conditions of use in dogs*—

* * * * *

(d) *Conditions of use in cats*—(1) *Amount.* 90-milligram tablet for cats up to 6 pounds of body weight, 204.9-milligram tablet for cats 7 to 15 pounds, a combination of tablets for cats over 15 pounds (a minimum of 13.6 milligrams per pound (30 milligrams per kilogram)).

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, directly or broken and mixed into wet food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

Dated: February 11, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–6412 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline and Tiamulin

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 Fermenta Animal Health Co. The NADA provides for the use of separately approved Type A medicated articles containing chlortetracycline and tiamulin in making Type C combination medicated feed. The feed is used in swine for treatment of bacterial enteritis and bacterial pneumonia and for control of swine dysentery. The regulations are also amended to increase the tolerance for tiamulin residue in swine liver.

EFFECTIVE DATE: March 14, 1997

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: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153–2314, filed NADA 141–011,

which provides for using separately approved Type A medicated articles containing chlortetracycline calcium complex equivalent to 50 to 100 grams per pound (g/lb) of chlortetracycline hydrochloride (CTC HCl) and 5 or 10 g/lb of tiamulin in making a Type C medicated swine feed. The feed contains a specific level of each animal drug as follows: Chlortetracycline calcium complex equivalent to approximately 400 g of CTC HCl per ton (g/t), varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline/lb of body weight daily, and tiamulin (as tiamulin hydrogen fumarate) 35 g/t. The feed is indicated for use in swine for treatment of swine bacterial enteritis and bacterial pneumonia caused by certain bacteria susceptible to CTC and for control of swine dysentery caused by certain bacteria susceptible to tiamulin. The NADA is approved as of August 20, 1996, and the regulations are amended in §§ 558.128 and 558.600 (21 CFR 558.128 and 558.600) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

These are new animal drugs used in Type A medicated articles to make Type B and C medicated feeds. Chlortetracycline and tiamulin are Category I drugs, which as provided in 21 CFR 558.4, do not require a licensed feed mill for making a Type B or C medicated feed from a Type A medicated article. Therefore, a licensed feed mill is not required for making a Type B or C medicated feed containing chlortetracycline in combination with tiamulin as in the approved subject NADA and in amended § 558.600.

Additionally, the safe concentrations and tolerances for tiamulin and chlortetracycline have been revised based on the new food consumption factors described in FDA's document entitled ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals'' (59 FR 37499, July 22, 1994). The revised tolerances for chlortetracycline were published in the Federal Register of December 23, 1996. The revised safe concentrations for total residues of tiamulin in edible swine tissues are 5 parts per million (ppm) in muscle, 15 ppm in liver, and 30 ppm in kidney and fat. These new safe concentrations for tiamulin residues in edible tissues correspond to a revised tolerance for tiamulin of 0.6 ppm for 8-*alpha*-hydroxymutilin (marker compound) in swine liver (target tissue). Accordingly, 21 CFR 556.738 is revised to increase the tolerance for the marker compound from 0.4 to 0.6 ppm.

The sponsor has demonstrated via residue depletion studies, using approved regulatory methods, that the depletion characteristics of the marker residues for each drug in the combination are not significantly modified and that the existing regulatory method for each drug in the combination is not interfered with by residues of the other drug. Therefore, the Center for Veterinary Medicine (CVM) concludes that the composition of each drug's residue is unchanged while in the combination. Accordingly, CVM is establishing a pre-slaughter withdrawal period of 2 days for use of this combination.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 (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 a 3-year period of marketing exclusivity beginning on August 20, 1996, because new clinical or field investigations (other than bioequivalence or residue studies), or human food safety studies (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant.

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

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 556.738 is revised to read as follows:

§ 556.738 Tiamulin.

A tolerance of 0.6 part per million is established for 8-*alpha*-hydroxymutilin (marker compound) in liver (target tissue) of swine.

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 558.128 is amended by adding new paragraph (c)(3)(xiii) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(c) * * *

(3) * * *

(xiii) Tiamulin in accordance with § 558.600.

5. Section 558.600 is amended by adding new paragraph (c)(4) to read as follows:

§ 558.600 Tiamulin.

* * * * *

(c) * * *

(4) *Amount per ton.* 35 grams of tiamulin (as tiamulin hydrogen fumarate), plus the equivalent of approximately 400 grams of chlortetracycline hydrochloride varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline per pound of body weight daily.

(i) *Indications for use.* Treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin.

(ii) *Limitations.* Feed continuously as sole ration for 14 days. Not for use in swine weighing over 250 pounds. Use as only source of chlortetracycline and tiamulin. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g.,

monensin, salinomycin, narasin, semduramicin, and lasalocid) as adverse reactions may occur. If signs of toxicity occur, discontinue use. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 000004 and 046573 in § 510.600(c) of this chapter.

Dated: February 6, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–6476 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 812

[Docket No. 92N–0308]

Investigational Device Exemptions; Disqualification of Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device regulations to include provisions for the disqualification of clinical investigators. These amended regulations parallel, with minor exceptions, the regulations for disqualification of clinical investigators of drugs, biologics, and animal drugs. The agency is finalizing this regulation to further implement its plan for consistent bioresearch monitoring procedures for all products regulated by FDA and to improve the remedies available to deal with clinical investigators who violate the law. This action is being taken under the Medical Device Amendments of 1976.

DATES: Effective May 13, 1997.

FOR FURTHER INFORMATION CONTACT: Rodney T. Allnutt, Center for Devices and Radiological Health (HFZ–310), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4718.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long intended to have clinical investigator disqualification procedures available for medical device investigations. Although the investigational device exemption (IDE) regulation part 812 (21 CFR part 812) allows FDA to initiate regulatory action against a study sponsor due to a noncompliant investigator, such as terminating the sponsor's IDE or imposing additional restrictions under the IDE, the IDE regulation did not expressly provide for clinical investigator disqualification. The proposed IDE regulation, published in the Federal Register of August 20, 1976 (41 FR 35282 at 35311), contained disqualification provisions for clinical investigators in proposed § 812.119 that were not included in the final IDE regulations published on January 18, 1980 (45 FR 3732), which apply to device investigations generally. Disqualification provisions were included, however, in part 813 (21 CFR part 813) on investigational exemptions for intraocular lenses (IOL's) in § 813.119 (42 FR 58874, November 11, 1977). The preamble to the final IDE regulation, published in the Federal Register of January 18, 1980 (45 FR 3732 at 3749), noted that proposed § 812.119 was being removed and would be addressed in FDA's final agency-wide regulation on the obligations of clinical investigators, which had been proposed in the Federal Register of August 8, 1978 (43 FR 35186). This agency-wide regulation, however, was never finalized.

In the Federal Register of October 6, 1993 (58 FR 52142), FDA issued a proposed rule to remove part 813, the regulation on investigational exemptions for IOL's. FDA received two comments in response to the proposed rule. These comments were addressed in the preamble to the rule that removed part 813, which was published in the Federal Register of January 29, 1997 62 FR 4164.

In the Federal Register of October 6, 1993 (58 FR 52144), FDA also published a proposed rule governing disqualification of clinical investigators of medical devices, to be added to part 812. The proposed rule was virtually identical to the regulation for disqualification of clinical investigators of IOL's, which would be removed with the proposed removal of part 813. In the proposed rule, however, FDA expressly invited comments on whether the procedures for disqualification of clinical investigators of medical devices should be identical, or virtually identical to the regulation for the disqualification of clinical investigators of drugs and biologics in § 312.70 (21 CFR 312.70). FDA stated that if comments persuaded the agency to revise the proposed rule to follow § 312.70 precisely or closely, the agency might issue a final rule which parallels § 312.70.

FDA received three comments stating an explicit preference for rules governing disqualification of investigators of drugs as specified in § 312.70, over the rules that had been proposed for disqualification of investigators of devices. Two other comments that did not specifically mention § 312.70 nevertheless suggested changes to the proposed rule that would make it more consistent with the drug investigator disqualification rule. The other three comments FDA received did not address this issue.

Two comments preferred § 312.70 to the proposed regulation because § 312.70 does not contain the perceived flaws found in the proposed regulation. These comments stated, e.g., that the threshold for disqualification in § 312.70 is set much higher and the terms are more clearly defined than in the proposed regulation. One of these comments requested that the Center for Devices and Radiological Health (CDRH) adopt § 312.70 in its entirety because of the perceived flaws in the proposed rule. That comment also noted that most medical device companies and investigators of devices are unfamiliar with § 312.70. Therefore, the comment recommended that FDA propose a rule similar to § 312.70 and give interested parties a chance to comment on the reproposal. The third comment stated that the regulation for disqualification of investigators of investigational new drugs is a better model because it is a relatively simple and clear regulation, it does not impose unfair and potentially harmful presumptions, and it would give FDA the immediate consistency it desires among product lines.

FDA has been persuaded by the comments that the regulation governing disqualification of investigators of medical devices should parallel the regulation for disqualification of investigators of drugs and biologics in § 312.70 (as well as the regulation for disqualification of investigators of animal drugs at § 511.1(c) (21 CFR 511.1(c))). This rule for disqualification of investigators of medical devices, therefore, adopts regulations that are basically the same as those governing disqualification of investigators of drugs, biologics, and animal drugs, with minor exceptions.

The agency has concluded, however, that a reproposal is unnecessary because the agency received sufficient and adequate comments to make a reasoned determination about the final rule and because the agency provided clear notice to interested persons that a final regulation paralleling § 312.70 would be adopted if the comments persuaded the agency that this approach represented the best option. (See the Federal Register of October 6, 1993, that stated ''FDA is giving notice that, if comments persuade the agency to revise the proposed rule to follow § 312.70 * * *