Bulletin MD11–28A082, dated May 14, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on July 24, 1996.

Issued in Renton, Washington, on July 1, 1996.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–17217 Filed 7–8–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline

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 five supplemental new animal drug applications (NADA's) filed by Hoffmann-LaRoche, Inc., Pfizer, Inc., ALPHARMA, Inc., ADM Animal Health & Nutrition Div., and PennField Oil Co. The supplemental NADA's provide for the safe and effective use of Type A medicated articles containing chlortetracycline (CTC) in the feed of chickens, turkeys, swine, sheep, and calves, beef and nonlactating dairy cattle for improved production efficiency and for control and treatment of certain bacterial diseases susceptible to CTC. The approvals reflect compliance with results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of the drug's effectiveness, and FDA's conclusions concerning that evaluation.

EFFECTIVE DATE: July 9, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: The following sponsors have submitted supplements to their approved NADA's:

- Hoffmann-LaRoche, Inc., Nutley, NJ 07110 (formerly held by American Cyanamid Co.), to NADA 48–761, which covers the Type A medicated articles: Aureomix® 293 (50 grams of chlortetracycline hydrochloride per pound (g CTC HCl/lb)) and Aureomycin® 50, 70, 80, 90, and 100 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- Pfizer, Inc., 235 East 42d St., New York, NY 10017, to NADA 92–286, which covers the Type A medicated articles CLTC® 10, 20, 30, 50, and 70 (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl) and to NADA 92–287, which covers the Type A medicated articles CLTC® 50 MR and 100 MR (contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ALPHARMA, Inc. (formerly A. L. Laboratories), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, to NADA 46–699, which covers the Type A medicated articles: CTC 100 MR (100 g CTC HCl/lb) and CTC 10, CTC 50, CTC 65, CTC 70, and Micro CTC 100 (contains CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl);
- ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508 (formerly Feed Specialties Co., Inc.), to NADA 48–480, which covers the Type A medicated article Chloratet™ 50 (contains CTC calcium complex equivalent to 50 g CTC HCI/lb); and
- PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, to NADA 138–935, which covers the Type A medicated articles: Chlortetracycline Premixes 50, 60, 70, 80, 100 (all contain CTC calcium complex equivalent to the indicated g/lb concentrations of CTC HCl), and 100 MR (100 g CTC HCl/lb).

The drug products were the subject of a NAS/NRC DESI evaluation of effectiveness (DESI 0113NV). The findings were published in the Federal Register of July 21, 1970 (35 FR 11646). NAS/NRC evaluated the drug products as probably effective for growth promotion and feed efficiency and for the treatment of animal diseases caused by pathogens sensitive to chlortetracycline. NAS/NRC stated that:

(1) Claims made regarding ''for prevention of'' or ''to prevent'' should be replaced with ''as an aid in the control of'' or ''to aid in the control of''; (2) claims for growth promotion or stimulation are disallowed and claims for faster gains and/or feed efficiency should be stated as ''may result in faster gains and/or improved feed efficiency under appropriate conditions''; (3) each disease claim should be properly qualified as ''appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)''; if the disease cannot be so qualified the claim must be dropped; (4) claims pertaining to egg production and hatchability should be changed to ''May aid in maintaining egg production and hatchability, under appropriate conditions, by controlling pathogenic microorganisms''; (5) the labels should warn that treated animals must actually be consuming enough medicated water or medicated feed to provide a therapeutic dosage under the conditions that prevail and, as a precaution, state the desired oral dose per unit of animal weight per day for each species as a guide to effective usage of the preparation in drinking water or feed; and (6) effective blood levels are required for each recommended dosage.

FDA concurred with the NAS/NRC findings, interpreting the phrase ''* * * cannot be so qualified * * *'' in above item (3) to mean ''* * * is not supported by adequate data * * *'' FDA reviewed all available effectiveness data of products subject to the evaluation and concluded that the data supported effectiveness for the control and treatment of certain bacterial diseases susceptible to CTC in chickens, turkeys, swine, sheep, calves, and cattle.

The NAS/NRC DESI evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites in food products derived from treated animals.

The five subject sponsors filed supplements that revised the labeling of their products to comply with the findings of the NAS/NRC review and FDA's conclusions concerning those findings. The supplemental NADA's were approved as of February 16, 1996. The revisions to § 558.128 (21 CFR 558.128) list the NAS/NRC and FDA-approved conditions of use for CTC-containing Type A medicated articles.

Products which comply with the NAS/NRC findings and FDA's conclusions regarding those findings are eligible for copying under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (see the eighth in a series of policy letters issued to facilitate implementation of GADPTRA that published in the Federal Register of August 21, 1991 (56 FR 41561). Accordingly, sponsors may now

obtain approval of abbreviated new animal drug applications (ANADA's) for these CTC Type A medicated articles.

FDA has incorporated within § 558.128 a warning against use of CTC feed in veal calves as part of a general effort to distinguish between ruminating calves and preruminating calves based on information indicating that withdrawal periods established in ruminating calves may not be adequate for preruminating calves.

Also, the agency has removed in § 558.128 the use of the fixed combination for chlortetracycline and sulfamethazine to treat beef cattle. FDA has recodified this approval in a separate section (§ 558.140 (21 CFR 558.140)), as has been done for other fixed combinations. In addition, the agency is using this occasion, of the DESI finalization of the CTC Type A medicated articles, to amend those portions of the regulations containing CTC combination feeds (see list in § 558.128(c)(5)) to revise the CTC claim language to make it consistent with the NAS/NRC and FDA-approved conditions of use.

Furthermore, the agency is deleting the citations for CTC in § 510.515 (21 CFR 510.515). Section 510.515 defines antibiotic drugs permitted in feed that were exempt from the requirement of certification. GADPTRA (Pub. L. 100–670) signed on November 16, 1988, removed the requirement for certification of antibiotic drugs for animal use. In fact, in a final rule published in the Federal Register of May 26, 1989 (54 FR 22741), the agency revoked the antibiotic procedural regulations. The published exemption constituted a sanction by the agency for use of the listed antibiotics. With the finalization of the DESI evaluation of the CTC products, the sanction is obsolete. Also, by deleting the CTC listing from § 510.515, the agency is correcting an error introduced when the regulation was published. Our records indicate that concurrent cites to oxytetracycline in § 510.515(b)(7)(i) and (b)(17)(i) were incorrect, as oxytetracycline was not considered a certifiable antibiotic animal drug; therefore, it was incorrectly listed in § 510.515.

In the Federal Register of October 21, 1977 (42 FR 56264), the then Bureau of Veterinary Medicine issued a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of certain NADA's listed in § 558.15, for most subtherapeutic uses of tetracycline (CTC and oxytetracycline) in animal feed. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in food animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of these supplements to finalize the DESI review process for CTC Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

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 (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)), these approvals for food-producing animals do not qualify for marketing exclusivity because the supplemental applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant.

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 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 510 and 558 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).

§ 510.515 [Amended]

2. Section 510.515 *Animal feeds bearing or containing new animal drugs subject to the provision of section 512(n) of the act* is amended in paragraph (b) by removing and reserving paragraphs (b)(7), (b)(17), (b)(25), and (b)(29); by redesignating paragraphs (b)(10) and (b)(13) as paragraphs (b)(1) and (b)(2); and in the table in paragraph (c) by removing entries 6, 7, and 8 for ''Chlortetracycline.''

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 558.55 is amended in the table in paragraph (d)(2) under entries (i), (ii), and (iv) by revising the items for ''Chlortetracycline 100 to 200'' and by adding new items for ''Chlortetracycline 200 to 400'' to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(2) * * *

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*
(ii) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*
(iv) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
* *	* *	*	*	*

* * * * *

5. Section 558.58 is amended in the table in paragraph (d)(1) by revising entry (iv) for the items ''Chlortetracycline 100 to 200'' and ''Chlortetracycline 200'' to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(d) * * *

(1) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	* *	*	*	*
(iv) * * *				
* *	* *	*	*	*
	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	
* *	* *	*	*	*

6. Section 558.128 is amended by revising paragraphs (a), (b), and (c)(1); by removing paragraphs (c)(2) and (c)(3); and by redesignating paragraphs (c)(4) and (c)(5) as paragraphs (c)(2) and (c)(3), to read as follows:

§ 558.128 Chlortetracycline.

(a) *Approvals.* Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

(1) 50 to 100 grams per pound to 000004 in § 510.600(c) of this chapter.

(2) 50 to 100 grams per pound to 000069.

(3) 50 to 100 grams per pound to 046573.

(4) 50 grams per pound to 012286.

(5) 50 to 100 grams per pound to 053389 .

(b) *Related tolerances.* See § 556.150 of this chapter.

(c)(1) It is used in feeds as follows:

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	000004, 000069, 012286, 046573, 053389
		2. Growing turkeys; increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	do
		3. Growing swine; increased rate of weight gain and improved feed efficiency.		do
(ii) 20 to 50 g/ton		Growing sheep; increased rate of weight gain and improved feed efficiency.		000004, 000069, 046573, 053389.
(iii) 50 to 100 g/ton		Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group *E. Streptococci* susceptible to chlortetracycline.		000004, 000069, 012286, 046573, 053389
(iv) 100 to 200 g/ton		Chickens; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	do

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/ton		Turkeys; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	do
(vi) 200 to 400 g/ton		1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	do
		2. Ducks; control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d.	000004
(vii) 400 g/ton		1. Turkeys; control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	000004, 000069, 012286, 046573, 053389
		2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.		do
		3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	do
(viii) 500 g/ton		Chickens; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.	do
(ix)10 mg/g of finished feed daily.		Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. *Warning:* ''Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.''	00004
(x) 0.1 mg/lb of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	000004, 000069, 012286, 046573, 053389
(xi) 0.5 mg/lb of body weight daily.		Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter.	do
(xii) 10 mg/lb of body weight		1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Treat for not more than 5 d; in feed excluding milk replacers; withdraw 10 d prior to slaughter except for 24 h for sponsor 046573; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	do

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
		2. Calves (up to 250 lb); treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline.	In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	
		3. Swine; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.	000004, 000069, 012286, 046573, 053389
(xiii) 25 mg/lb of body weight		Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	do
(xiv) 25 to 70 mg/head/day		Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.	Include on labeling the warning: ''A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.''	000004, 000069, 012286, 046573, 053389
(xv) 70 mg/head/day		Growing cattle (over 400 lb) increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	do	do
(xvi) 80 mg/head/day		Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.		000004, 000069, 046573, 053389
(xvii) 350 mg/head/day		1. Cattle (under 700 lb); control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter.	000004, 000069, 012286, 046573, 053389
		2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	do	do

* * * * *

7. New § 558.140 is added to subpart B to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Approvals.* Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 000004 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day.* Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter.

8. Section 558.175 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 558.175 Clopidol.

* * * * *

(c) * * *

(2) * * *

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus chlortetracycline 100 to 200 grams.

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* E. *acervulina, E. maxima, E. brunetti,* and *E. mivati*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(*b*) *Limitations.* Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.

* * * * *

9. Section 558.195 is amended in the table in paragraph (d) in the entry for ''27.2 (0.003pct)'' by removing the item for ''Chlortetracycline 200'' and adding in its place an item for ''Chlortetracycline 100 to 200'' and an item for ''Chlortetracycline 200 and 400'' to read as follow:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27.2 (0.003pct)				
* *	*	* *	*	*
	Chlortetracycline 100 to 200.	Chickens; for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; in low calcium feed containing 0.8 pct. of calcium; feed continuously 7 to 14 days.	011526
	Chlortetracycline 200 to 400.	Chickens; for the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati , E. acervulina, E. maxima,* and *E. brunetti*; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	do	011526
* *	*	* *	*	*

10. Section 558.274 is amended in the table in paragraph (c)(1) under entry (i) by revising the item for ''Chlortetracycline 100 to 200'' and by adding a new item for ''Chlortetracycline 200 to 400''; and under entry (ii) by removing the item for ''Chlortetracycline 100 to 200'' and adding in its place an item for ''Chlortetracycline 400'' to read as follows:

§ 558.274 Hygromycin B.

* * * * *

(c) * * *

(1) * * *

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) * * *				
* *	*	* *	*	*
	Chlortetracycline 100 to 200.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter.	
	Chlortetracycline 200 to 400.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*H. Gallinae*), and capillary worms (*Capillaria obsignata*); control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	do	
* *	*	* *	*	*
(ii) * * *				

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
	Chlortetracycline 400.	Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Withdraw 15 d before slaughter.	
* *	*	* *	*	*

* * * * *

11. Section 558.515 is amended by revising paragraphs (d)(1)(iii), (d)(1)(iv), and (d)(1)(v)(*b*) to read as follows:

§ 558.515 Robenidine hydrochloride.

* * * * *

(d) * * *

(1) * * *

(iii) *Amount per ton*. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 to 200 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(iv) *Amount per ton*. Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 to 400 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E.* necatrix; control of chronic respiratory disease (CRD) and air sac infection caused by M. *gallisepticum* and *E. coli* susceptible to chlortetracycline.

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously as sole ration up to 14 days.

(v) * * *

(*b*) *Limitations*. Withdraw 5 days prior to slaughter; do not feed to chickens producing eggs for human consumption; feed continuously up to 5 days.

* * * * *

12. Section 558.530 is amended by revising paragraph (a); by redesignating paragraphs (d)(2), (d)(3), and (d)(4) as paragraphs (d)(4), (d)(5), and (d)(6), by adding new paragraphs (d)(2) and (d)(3); and by revising newly redesignated paragraph (d)(4) to read as set forth below, and in newly redesignated paragraph (d)(6) by redesignating paragraphs (d)(6)(i)(*a*) through (*d*) as paragraphs (d)(6)(i)(A) through (D).:

§ 558.530 Roxarsone.

(a) *Approvals*. Type A medicated articles: (1) 10, 20, and 50 percent to 011526 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

(2) 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

* * * * *

(d) * * *

(2) *Growing chickens*—(i) *Grams per ton*. Roxarsone, 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(ii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 100 to 200.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 200 to 400.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 500.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.

(B) *Limitations*. See paragraph (d)(2)(i)(B) of this section except feed for 5 days.

(3) *Growing turkeys*—(i) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. Do not feed to turkeys producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing season.

(ii) *Grams per ton*. Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline 200.

(A) *Indications for use*. For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by

M. synoviae susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(iv) *Amount.* Roxarsone 22.7 to 45.4 grams per ton (0.0025 to 0.005 percent) plus chlortetracycline, 25 milligrams per pound of body weight daily.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(3)(i)(B) of this section except that the drug should only be fed continuously for 7 to 14 days.

(4) *Growing-finishing swine*—(i) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed continuously throughout growing season.

(ii) *Grams per ton.* Roxarsone 22.7 to 34.1 (0.0025 to 0.00375 percent) plus chlortetracycline, 400 (to administer 10 milligrams per pound of body weight).

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; feed for not more than 14 days.

(iii) *Grams per ton.* Roxarsone 181.5 (0.02 percent).

(A) *Indications for use.* For the treatment of swine dysentery.

(B) *Limitations.* Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source or organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.

(iv) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For the treatment of swine dysentery; increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

(v) *Grams per ton.* Roxarsone, 181.5 (0.02 percent) plus chlortetracycline, 400.

(A) *Indications for use.* For the treatment of swine dysentery; treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(4)(iii)(B) of this section.

* * * * *

13. Section 558.680 is amended in the table in paragraph (c)(1) under entries (i) and (ii) by revising the item for ''Chlortetracycline 100 to 200''; by removing the item for ''Chlortetracycline 200'' and adding in its place an item for ''Chlortetracycline 200 to 400'' to read as follows:

§ 558.680 Zoalene.

* * * * *

(c) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) * * *			
* *	*	* *	* *
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 200 to 400.	Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
* *	*	* *	* *
(ii) * * *			
* *	*	* *	* *
	Chlortetracycline 100 to 200	Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Chlortetracycline 200 to 400	Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
* *	*	* *	* *

* * * * *

Dated: June 13, 1996.

Andrew J. Beaulieau,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–17169 Filed 7–8–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 941

[Docket No. FR–3919–N–04]

Office of the Assistant Secretary for Public and Indian Housing; Public/Private Partnerships for the Mixed-Finance Development of Public Housing Units Extension of Public Comment Deadline on Interim Rule

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Extension of Public Comment Deadline on Interim Rule.

SUMMARY: On May 2, 1996, HUD published an interim rule that added a new subpart F to the public housing development program at 24 CFR part 941. Under this new subpart, a public housing authority (PHA) was authorized to provide to a non-PHA entity public housing development and operating funds for the development and operation of the resulting public housing units. In addition, the rule clarified that replacement public housing units for public housing units that have been demolished could be built on the original public housing site, or in the same neighborhood, if the number of such replacement units was significantly fewer than the number of units demolished. The May 2, 1996 interim rule provided for the public comment period to expire on July 1, 1996. This notice extends the public comment period to September 15, 1996.

DATES: Comment Due Date: September 15, 1996.

ADDRESSES: Interested persons are invited to submit comments on the interim rule to the Office of the General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Bill Flood, Office of Capital Improvements, Office of Public and Indian Housing, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4134, Washington, DC 20410–0500, telephone (202) 708–1640, ext. 4185; (TTY): (202) 708–9300 or 1–800–877–8339. (Except for the ''800'' telephone number, these are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On May 2, 1996, HUD published an interim rule (61 FR 19708) that added a new subpart F to the public housing development program at 24 CFR part 941. Under this interim rule, a PHA is authorized to provide a portion of its HUD-awarded development and operating funds to a non-PHA entity for the entity to own, develop and operate the resulting public housing units. The non-PHA entity may develop and operate the public housing units using public and private financing (i.e., as a ''mixed-finance'' project), and to develop solely public housing units or a combination of public housing, shallow subsidy, and market rate units.

In addition, the May 2, 1996 interim rule added a new paragraph (c)(3) to HUD's existing site and neighborhood standards at § 941.202. This purpose of this provision was to clarify HUD's existing authority to approve the building of replacement public housing units for public housing units that have been demolished on either the original public housing site, or in the same neighborhood, if the number of such replacement public housing units is significantly fewer than the number of public housing units demolished. This authority was affirmed by the passage of section 1002(a)(9) of Pub. L. 104–19 (approved July 27, 1995) which explicitly authorized HUD to approve the building of replacement public housing units under such circumstances.

Extension of Public Comment Period

The May 2, 1996 interim rule provided for a 60-day public comment period which is scheduled to close on July 1, 1996. Because of the significant public interest in this rule, HUD is extending the public comment period to September 15, 1996.

Dated: June 28, 1996.

Michael B. Janis,

General Deputy, Assistant Secretary for Public and Indian Housing.

[FR Doc. 96–17177 Filed 7–8–96; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS). The Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that a prior certification of noncompliance for USS SEAWOLF (SSN 21) should be amended. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: March 4, 1996.

FOR FURTHER INFORMATION CONTACT: Captain R. R. Pixa, JAGC, U.S. Navy; Admiralty Counsel, Office of the Judge Advocate General Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.